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Nos. 95-754, 95-886

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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Brief For The Medical Device Manufacturers Association As *Amicus Curiae* Supporting Petitioner/Cross-Respondent Medtronic, Inc.

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BRIEF FOR THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION AS *AMICUS CURIAE* SUPPORTING PETITIONER/CROSS-RESPONDENT MEDTRONIC, INC.

STATEMENT OF INTEREST

The Medical Device Manufacturers Association ("MDMA") is a national trade association of over one hundred mostly small manufacturers of medical devices, diagnostic products and health care information systems. To improve the quality of patient care, MDMA encourages development of new medical technology and availability of innovative products. MDMA therefore pursues its members' interests in the laws and regulations enforced by the United States Food and Drug Administration ("FDA"), including how those laws and regulations are interpreted and applied in the courts.

The decision in this case will profoundly impact MDMA's members. In the 1976 Medical Device Amendments ("MDA")

to the Federal Food, Drug and Cosmetic Act ("FDCA"), Congress expressly preempted all state legal requirements relating to medical devices that were different from, or in addition to FDA requirements. 21 U.S.C. §360k(a). A primary reason Congress did so was the adverse effect of dual state and federal medical device requirements on "small manufacturer[s] of medical devices"[1] — MDMA's membership. Twenty years later, this Court is being asked to upset this congressional policy by exempting from preemption a major source of state-imposed legal requirements, common law tort actions.

MDMA files this brief in support of petitioner/cross-respondent Medtronic, Inc. Written consents have been filed with the Clerk.

SUMMARY OF ARGUMENT

Cross-petitioners Lora and Michael Lohr (hereafter referred to as "plaintiffs") seek damages for personal injuries that they allege were caused by a cardiac pacemaker lead made by petitioner Medtronic, Inc. They claim the leads were defectively designed, manufactured, and assembled, and that Medtronic failed to provide adequate warnings and violated FDA requirements. The Court of Appeals held that all of these claims were preempted by the MDA except those relating to design. *Amicus* MDMA submits that the Court of Appeals failed to recognize the full extent of federal medical device regulation. Had the Court of Appeals understood how pervasive and detailed that scheme is, it would have held all of plaintiffs' claims preempted.

In the following argument *amicus* will first show that Congress understood that the distinctive nature of medical device production warranted exclusive federal regulation. Because the requisite federal oversight would burden what was and is an innovative industry populated by small companies with limited financial resources, Congress balanced the scale by preempting parallel state legal requirements.

1. S. Rep. No. 33, 94th Cong., 2d Sess. at 18 (1976) (reprinted at 1976 U.S.C.C.A.N. 1070, 1087).

Next, *amicus* will describe the federal regulatory scheme, demonstrating how it necessarily preempts plaintiffs' claims, including the design claim that the Court of Appeals held not preempted. Preemption flows from federal "requirements" — a broader term than "regulations" — so to decide this case, this Court must have before it the full scope of federal medical device requirements, including those imposed by the FDA's device clearance process, its extensive post-market requirements, and its enforcement activity.

Finally, *amicus* will explain why plaintiffs cannot escape federal preemption by bringing state-law claims that manufacturers violated requirements imposed by federal law. Congress deleted from the MDA a preemption exception that would have preserved this type of claim, and preemption reinforces both the statute's prohibition of private enforcement and grant of prosecutorial discretion to the FDA. Nor can state tort litigation be consistent with FDA requirements in practice, since any contested case would inevitably involve opposing interpretations of what those requirements are.

Amicus submits that the judgment of the Court of Appeals should be affirmed except insofar as it did not preempt plaintiffs' design-related claim. As to that claim, the judgment should be reversed, and judgment entered for Medtronic.

ARGUMENT

In enacting the MDA in 1976, Congress sought to protect public health by balancing the need for regulation of medical devices with the need for development of new and improved devices without excessive cost or delay.[2] A critical part of that balance — preemption of state legal requirements in favor of intensive FDA regulation of medical devices — is now before the Court.

2. *See* S. Rep. No. 33 at 5 (1976) ("Although many lives have been saved or improved by the new discoveries, the potential for harm to consumers has been heightened by the critical medical conditions in which sophisticated modern devices are used and by the[ir] complicated technology"), at 6 (recognizing both "benefits that medical research and experimentation to develop devices offers" and a "need for regulation to assure that

I. The Medical Device Industry Retains The Nature That Led Congress To Preempt State Medical Device Requirements.

The MDA's legislative history is replete with Congressional recognition of the distinctive structure of the medical device industry. The industry's defining trait is constant innovation. "[T]he state of the art in the medical devices field is rapidly changing and continually improving." S. Rep. No. 33, 94th Cong., 2d Sess. at 11 (1976) (reprinted at 1976 U.S.C.C.A.N. 1070, 1081). Congress understood that "devices [are] subject to rapid obsolescence." *Id.* at 16 (reprinted at 1976 U.S.C.C.A.N. 1085). Accordingly, Congress "developed a balanced regulatory proposal intended to assure that the public is protected from unsafe and ineffective medical devices . . . and that innovations in medical device technology are not stifled by unnecessary restrictions." H.R. Rep. No. 853, 94th Cong., 2d Sess. at 12 (1976).[3] The MDA was drafted to foster innovation — "to permit new or improved devices to be marketed without delay so that the public may have such beneficial devices available to them as soon as possible." S. Rep. No. 33 at 14 (reprinted at 1976 U.S.C.C.A.N. 1083). Plaintiffs may disagree with how Congress struck its balance, but reweighing the interests involved is for Congress, not the courts.

NOTES *(Continued)*

the public is protected"), at 7 ("a balance [should] be struck between the need for continuing research and the need for improved patient protection"), at 13 (intent that "innovation is not stifled" and that " 'quack' devices or devices known to be unsafe or ineffective" not be allowed) (reprinted at 1976 U.S.C.C.A.N. 1074, 1075, 1076, 1083); H.R. Rep. No. 853, 94th Cong., 2d Sess. at 10 (1976) ("protection against unsafe, unproven, ineffective and experimental medical devices is counterbalanced by an equally strong conviction that excessive . . . regulation would stifle progress").

3. *See* S. Rep. No. 33 at 13 ("innovation"), 14 ("rapidly changing nature"), 15 ("stage of rapid development;" "rapidly changing") (citation and quotation marks omitted) (reprinted at 1976 U.S.C.C.A.N. 1083, 1084).

An inherent consequence of rapid innovation in any industry is the presence of many relatively small companies. Both the Senate and the House appreciated the impact of the MDA on the small enterprises that constitute the great majority of the medical device industry. The Senate took "specific note" of concerns about:

> the impact of this legislation on the small manufacturer of medical devices. The concern stemmed from the importance of the small innovative manufacturer in the invention and development of new medical devices and the inability of these firms, because of limited financial resources, to sustain the high level of administrative costs demanded of a highly regulated industry . . . .

S. Rep. No. 33 at 18 (reprinted at 1976 U.S.C.C.A.N. 1087). The Senate recognized "these concerns a[s] legitimate . . . consistent with the public's need for safe and effective medical devices." *Id.* It expressed "confiden[ce] that the administration of this new law will also take into account the need to preserve the small manufacturer's role in the device industry. *Id.* The House agreed:

> [The MDA] reflects the need to develop innovative new devices . . . . [I]t recognizes that this significant new authority must not unnecessarily burden the small manufacturers of medical devices who have been responsible for the development of a host of important and innovative devices.

H.R. Rep. No. 853 at 12. *See id.* at 56 ("cognizant of the potentially detrimental economic impact of this legislation . . . on small device manufacturers").

One way Congress ameliorated the potential undue burden upon small device manufacturers was to couple comprehensive federal regulation with preemption of state legal requirements. 21 U.S.C. §360k(a); *see* H.R. Rep. No. 853 at 45. Only if the FDA expressly found that a state requirement "would constitute a useful supplement to federal regulation," H.R. Rep. No. 853 at 45, could any state legal requirement be exempted from preemption. *See* §360k(b).

The concerns motivating Congress in 1976 remain valid today. Congress heard testimony about the current structure of the medical device industry on March 30, 1995:

> There are approximately 5,000 distinct generic types of devices and more than one million brands, models and sizes. . . . In the United States, this disparate collection of entities is produced by approximately 5,000 manufacturers. The vast majority of U.S. device manufacturing firms are quite small and very specialized and have fewer than 50 employees. There are relatively few large national or multinational manufacturers. . . .

H.R. Serial No. 18, 104th Cong., 1st Sess. at 22 (Mar. 30 1995) (statement of Joel J. Nobel, M.D.).[4] Rapid innovation limits the life cycle of medical devices, providing only a short time for recouping development expenses and achieving profitability:

> Most devices are typically developed in 1 to 3 years, become obsolete, and are off the market in 3 to 7 years. This temporal distinction is critical. . . . When approval time consumes almost half of the product's life cycle, something is seriously out of balance. . . . The consequences of approval delays may impact patients, as well as manufacturers and investors, negatively.

H.R. Serial No. 18 at 26 (Dr. Nobel) (emphasis omitted).

As the FDA's medical device requirements have become increasingly comprehensive and detailed, the financial burden of compliance has similarly grown.[5] Federal preemption of

4. *See 1994 Reference Guide for the Health Care Technology Industry* at 4 (Health Care Technology Institute 1994) (72.1% of FDA-registered device manufacturers had under 50 employees and 96.4% had fewer than 500 employees).

5. Small device manufacturers need venture capital to finance new products, but they "face[] increased challenges in attracting venture interest as a result of FDA's expanded efforts to govern market clearance for medical devices." *Trends in Venture Capital Funding for the Medical Device Industry* at 3 (Health Care Technology Institute Mar. 1994). A "growing" number of "regulatory hurdles in the path of innovation" have contributed to a recent decline in venture capital investment in the medical device field. *1995 Reference Guide for the Health Care Technology Industry* at 15 (Health Care Technology Institute 1995). *See also* H.R. Serial No. 18 at 53 (34% venture capital decline in 1993; also describing decline in public offerings by device companies between 1992 and 1995) (statement of Ali Gallagher).

state law is thus more important than ever to small device manufacturers. It is the most significant way that Congress alleviated the financial burden of its all-encompassing federal regulatory scheme.

II. Applicable Federal Requirements Preempt All Of Plaintiffs' Claims.

The 1938 FDCA dealt mostly with food and drugs. The federal government received exclusive enforcement authority and discretion to decide whether and how to prosecute violations. 21 U.S.C. §§336-37. The 1976 MDA expanded the FDA's power, giving the Agency comprehensive regulatory authority over medical devices. *See generally* 21 U.S.C. §§360c-360l. The MDA did not dilute either sole federal enforcement authority or federal prosecutorial discretion.

The MDA gives preemptive force to any federal requirement that "relates to" either device "safety or effectiveness" or to "any other matter included in a requirement applicable to the device." §360k(a). Congress used the broad term "requirement" in preference to "regulation" or other more narrow language. *See, infra,* at 20 & n. 29. Thus, application of preemption must reflect not only FDA's formal regulations — extensive in their own right — but also FDA requirements not contained in regulations. *See* 42 Fed. Reg. 30383, 30384 (FDA Jun. 14, 1977) (preemption may arise from "regulatory or administrative action").

A. *FDA Requirements Applicable To Medtronic's Device Through Its Clearance For Marketing*

The regulatory status of the Medtronic cardiac pacemaker lead at issue in this case is undisputed — the FDA cleared it for marketing via a process called "510(k)" pre-

market notification. *See* 21 U.S.C. §360(k) (§510(k) of the MDA); *see also* §360c(f,i) (detailing 510(k) criteria). The FDA can clear any device (of any classification[6]) through this process by finding it "substantially equivalent" to a device (called a "predicate device") that either: (1) was in commercial distribution prior to passage of the MDA in 1976, or (2) is otherwise being legally marketed. *Id.;* 21 C.F.R. §807.81(a). Absent an FDA exemption, the MDA mandates that these 510(k) "requirement[s]" remain "applicable to a device." 21 U.S.C. §360j(a) (referencing §360(k)). There is no such exemption here, so the 510(k) clearance process is one source of preemptive requirements applicable to this device.

Manufacturers seek 510(k) clearance by submitting "premarket notifications" to the FDA. These must contain: (1) proposed labeling; (2) a statement of design similarities and differences compared to the predicate device; (3) a description (which may include photographs and engineering drawings) of significant physical and performance characteristics of the device, including its design, materials and physical properties; (4) the medical conditions for which the device is "intended" to be used; (5) information showing how the "design, material, chemical composition, or energy source" of the device is substantially equivalent to the predicate device, and (6) "[a]ny additional information" the FDA requires to determine substantial equivalence. 21 C.F.R. §§807.87(e-h); 807.92(a)(4-6).

Some of these 510(k) criteria were formally "codified" in 1990,[7] but all existed as FDA requirements well before that time. A 1986 FDA guidance document (reproduced as Appendix "A") "outlines requirements for premarket notification review" for "consistent application" by Agency reviewers.

6. The FDA assigned Class III status to the Medtronic pacemaker leads. *See* 21 C.F.R. §870.3680. 510(k) clearance imposes essentially the same requirements upon any device, regardless of its resulting classification. *See* 21 C.F.R. Part 807, Subpart E; M. Herrmann & G. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 Food & Drug L.J. 1, __ (1996) (forthcoming).

7. *See* H.R. Rep. No. 808, 101st Cong., 1st Sess. at 24 (reprinted at 1990 U.S.C.C.A.N. 6305, 6317) (1990 Safe Medical Devices Act "codifies FDA's current practice regarding the use of the 510(k) procedure").

App. "A" at 1a. This guidance document elaborates the extensive requirements that 510(k) clearance imposes on both device design and labeling:

- Manufacturers must "compare[] the new device to a marketed device of a similar type." App. "A" at 4a.
- This comparison must include "technological characteristics, (i.e., same materials, design, energy source, etc.)." *Id.* at 6a.
- All changes to "technological characteristics" must be evaluated by "accepted scientific methods" to determine if they raise "new questions" about safety or effectiveness. *Id.*
- The "therapeutic or diagnostic statements" in the labeling and promotional materials for both the predicate and new devices must demonstrate the same "intended use" for both devices. *Id.* at 7a.
- The manufacturer must demonstrate the same intended use and that "any changes in labeling are immaterial." *Id.* at 10a.
- The FDA conducts a detailed evaluation of design changes in determining whether to grant 510(k) clearance. *Id.* at 10a-11a.[8]
- The FDA "always require[s] descriptive data. . .[concerning] a new device's intended use, physical composition, method of operation, specifications, performance claims, etc." *Id.* at 16a.

8. The 1986 guidance document cites examples of actual FDA evaluations of device design changes: modified visual displays for electrocardiographs, modified connector designs for penile prosthetic pumps, substitution of computerized features for manually operated features, substitution of one type of filtration membrane for another, "minor change[s] in design" of heart valve shape and composition, use of electrical shocks versus sound waves for kidney stone fragmentation, and smooth versus contoured surfaces for hip implants. *Id.* at 10a-15a.

- If there is "an important descriptive difference," the FDA will normally require performance testing data. *Id.*[9]

As the FDA's 1986 guidance document illuminates, 510(k) clearance involves a complex and detailed FDA evaluation of both the design and labeling of medical devices. In its searching clearance inquiry, the FDA frequently calls for "additional information." 21 C.F.R. §807.87(h). Compliance with such requests is mandatory or the FDA "consider[s] the premarket notification to be withdrawn." *Id.*[10] To explain the complicated operation of 510(k) clearance, the FDA has prepared a detailed "flow chart" describing the process. The FDA's flow chart is reproduced at Appendix "B".[11]

The Court of Appeals limited its consideration to the FDA's regulations. It failed to consider how, in practice, the FDA imposes design-related requirements through the 510(k) process. The Court of Appeals erred when it concluded that state-law tort claims challenging device design were not preempted as "different from or in addition to" "requirement[s]" imposed by 510(k) clearance. §360k(a).

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9. Pacemaker leads — the device at issue in this case — are cited in the FDA guidance document as an example of when performance testing data is required by the 510(k) process. *Id.* at 17a.

10. The record contains Medtronic's affidavit listing the additional information FDA required here. Swanson Aff. ¶8. Other examples of "additional information" that the FDA has demanded from MDMA's members include: engineering drawings; fatigue and other test results; sterilization methods, including process validation of such methods; identification of other devices with which a device may be used; lists of the applicant's previously cleared devices; dimensional comparisons with the predicate device; performance information; device samples; design and intended use memoranda; "worst case" scenarios; drawings or descriptions of how multicomponent device systems are assembled; photographs of devices in use; enlarged photographs; ASTM materials standards; profile analysis for implantable devices; surgical technique manuals; descriptions of device packaging; lists and descriptions of instruments to be used with devices; and summaries of information supporting safety and effectiveness.

11. The flow chart is from HHS Publication FDA 95-4158, *Premarket Notification 510(k): Regulatory Requirements for Medical Devices*, App. C at C-16 (U.S. Govt. Printing Off. Aug. 1995).

A second FDA guidance document, No. G91-1 (reproduced at Appendix "C"), enumerates 510(k) requirements for device labeling. This document serves two purposes: "formal[] guidance to [FDA] reviewers concerning their review of labeling in device marketing submissions" and "for industry use in preparing device labeling." App. "C" at 1c. Guidance document G91-1 further shows the extensive labeling requirements imposed by the FDA's device clearance process.

Guidance document G91-1 specifies that proposed labeling submitted to the FDA for 510(k) clearance must address:

- **Safety and effectiveness** — (1) the population of device users, (2) each medical condition that either the labeling or advertising suggests as a use for the device, (3) relative benefits and risks, and (4) reliability. App. "C" Part II.
- **Indications for use** — (1) the medical conditions for which use is indicated, (2) the target population, (3) whether the intended use is curative, palliative, or diagnostic, and (4) special instructions for long-term use. In the indications, the FDA may require specific disclaimers of effectiveness for particular medical conditions. *Id.* Part III.
- **Contraindications** — all situations where the risk of a device outweighs any possible benefit. *Id.* Part IV.
- **Warnings** — all serious adverse reactions, potential safety hazards and limitations on use as well as steps to be taken if such a risk occurs. A warning is also "appropriate" where a common use of a device is not proven effective and is associated with a serious risk. *Id.* Part V.
- **Precautions** — (1) protective clothing, (2) special laboratory tests, or (3) any other particular procedures needed for the safe and effective use of the device. *Id.* Part VI.
- **Special patient populations** — concerns unique to users such as (1) pregnant women, (2) children, or (3) patients with anatomic or physiological limitations. *Id.* Part VII.

- **Adverse reactions** — any undesirable effects associated with use of the device, as well as steps to be taken if such an effect occurs. *Id.* Part VIII.

Guidance document G91-1 imposes additional requirements "upon prescription devices" — those the FDA does not allow to be used without a physician's prescription. *Id.* Part IX.[12] The document also details when the FDA will require that a manufacturer provide special device labeling to be given directly to lay patients. *Id.* Part XI.

The FDA's authority over labeling of 510(k) devices is so pervasive that the Agency actually rewrites the labeling proposed by device manufacturers. Appendix "D" exemplifies the extensive editorial revisions that the FDA makes to labeling submitted for 510(k) clearance.[13] The FDA's exercise of exacting control over device labeling during 510(k) review supports affirmance of the Court of Appeals' holding that all state-law tort claims attacking information contained in or omitted from medical device labeling are expressly preempted.

B. *FDA Post-Marketing Requirements Applicable To The Medtronic Device*

The FDA continues to impose requirements upon 510(k) medical devices even after they are cleared for marketing. The FDA has many post-market requirements through which it retains control over device manufacture, design, and labeling.

1. MANUFACTURING REQUIREMENTS. The FDA's extensive Good Manufacturing Practice ("GMP") regulations

12. Prescription device labeling must state its prescription-only status and include "information for use including indications, effects, routes, methods, frequency and duration of administration, and any relevant hazards, contraindications, side effects and precautions" for all purposes for which it is advertised or represented. *Id.*

13. Expanding FDA requirements are also reflected in the time the Agency needs to act on requests to market devices. *See* 1995 Reference Guide at 15-21 (FDA pre-market approval took 262 days in 1988 and 649 days in 1994; the time for FDA action on 510(k) applications increased from 64 days to 184 days during same period).

control device manufacturing. *See* 21 U.S.C. §360j(f)(1); 21 C.F.R. Part 820. Non-compliance with GMPs "adulterates" a device. 21 U.S.C §351(h). GMPs, like the 510(k) process, are MDA "requirement[s]" that "apply to [] device[s]." *Id.* §360j(a). GMPs govern all aspects of device manufacturing and distribution, including: quality assurance, 21 C.F.R. §820.5; organization, §820.20; personnel, §820.25; buildings, §§820.40, 820.120(b); environmental control, §820.46; sanitation, §820.56; production equipment, §820.60; measurement equipment, §820.61; components, §§820.80-.81; conformity to manufacturing specifications, §§820.100-.101; reprocessing, §§820.115-.116; labeling, §820.120-.121; packaging, §820.130; storage and shipment, §820.150; installation, §820.152; inspection, §§820.160-.161; failure investigation, §820.162; complaint files, §820.198; and record keeping. §§820.180-.195. In addition, the FDA considers implanted devices such as pacemaker leads to be critical devices, 21 C.F.R. §820.3(f), and subjects them to still more GMP requirements.[14]

The GMPs are "intended to assure that. . .devices will be safe and effective." 21 C.F.R. §820.1. They are enforced by regular FDA inspections of device manufacturing facilities and records, which occur without advance notice. 21 U.S.C. §374(a,e). FDA facility inspections are thorough. *See FDA Compliance Program Guidance Manual* §7382.830, Attachment A at 8-13 (FDA May 1994) (describing scope of routine inspection). Over half of all facility inspections result in some finding of deficiency. 1 A. Levine, *FDA Enforcement Manual* ¶302 at 4 (Thompson Publishing Group May 1995).[15] An uncorrected deficiency results in FDA enforcement action against the manufacturer or its adulterated devices. 21 U.S.C. §351(h); 21 C.F.R. §820.1(a).

14. *See* 21 C.F.R. §820.81(a) (components); §820.81(b) (changes to components); §820.101 (manufacturing procedures); §820.116 (reprocessing); §820.121(a) (control numbers); §820.121(b) (proofreading of labeling); §820.151 (shipping); §820.161 (inspection); §§820.182, 820.185, 820.195 (record keeping).

15. In fiscal year 1994, FDA conducted 3,231 medical device inspections, of which 1,742 (54%) generated an "adverse" finding. *Id.*

The GMP requirements are comprehensive, and they applied to the Medtronic device. The Court of Appeals correctly held that plaintiffs' manufacturing-related claims were preempted.

2. LABELING REQUIREMENTS. The FDA exercises its power to prohibit device "misbranding" by imposing requirement[s] . . . applicable to [] device[s] under the MDA. 21 U.S.C. §360j(a) (referencing *id.* §352). The most stringent FDA labeling requirements apply to prescription-only devices, such as pacemaker leads. *See* 21 C.F.R. §§801.109(c-d); 801.15 (governing prominence). Another regulation, §801.4, defines "intended use" and delineates the uses for which §801.109 information must be included — and, conversely, excluded — on device labeling. *Id.* §801.4[16] At any time, the FDA can demand a copy of all labeling for any device. 21 C.F.R. §807.31(e).

The GMPs also impact device labeling.[17] Device manufacturers must report to the FDA in writing all incidents of the sort claimed here — where a device malfunctioned unexpectedly or contributed to serious injury or death. *Id.* §803.24. Based upon this information, FDA can take remedial action, including requiring "relabeling." *Id.* §803.3(g). The FDA can require the addition of contraindications ("do not use") or precautions ("use with caution") to device labeling. *Id.* §801.109. Should the FDA conclude that a medical device endangers public health, it has broad powers to require any labeling change that it sees fit. *Id.* §895.25(a-b).

The FDA also regulates labeling informally, particularly promotional activities by device manufacturers. Relying on *Kordel v. United States,* 335 U.S. 345, 349-50 (1948), the FDA

16. While physicians may use devices in ways other than their FDA-designated "intended use," *e.g.,* 59 Fed. Reg. 59820, 59821 (FDA Nov. 18, 1994), manufacturers may label and promote only intended uses recognized by the FDA. 21 C.F.R. §§801.4; 801.109.

17. *See* 21 C.F.R. §§820.20(a)(2), 820.120, 820.121, 820.181(d), 820.182(b). The labeling impact of GMPs is addressed in HHS Publication FDA 89-4203, *Labeling Regulatory Requirements for Medical Devices* at 17-20 (U.S. Govt. Printing Off. Aug. 1989).

expansively views its authority over "labeling" to encompass promotional activity.[18] Promotion "by or on behalf of the companies that market [medical devices] ha[s] traditionally been viewed by FDA as subject to regulation under the labeling and advertising provisions of the [FDCA]." 57 Fed. Reg. 56412, 56412 (FDA Nov. 27, 1992).[19]

The FDA's continued post-market oversight of device labeling is another ground for affirming the Court of Appeals' dismissal of plaintiffs' warning and information-based tort claims.

3. DESIGN REQUIREMENTS. An 510(k) clearance invests the FDA with ongoing control of the design of the cleared device by virtually freezing the cleared design. Any design change "that could significantly affect safety or effectiveness" requires a new 510(k) submission. 21 C.F.R. §807.81(a)(3)(i). Thus, any alternative design that plaintiffs might propose for the Medtronic pacemaker leads would, in the absence of further 510(k) clearance, be illegal under the MDA.

Minor design changes not requiring a new 510(k) are still subject to other FDA requirements. The GMPs require device manufacturers to validate or qualify all changes to device

18. Recent examples of FDA requirements imposed on promotion as "labeling" include: 57 Fed. Reg. 56412 (FDA Nov. 27, 1992) (draft policy statement regarding certain types of promotion); 59 Fed. Reg. 59820 (FDA Nov. 18, 1994) (seeking comments on draft policy statement); 60 Fed. Reg. 63384 (FDA Dec. 8, 1995) (guidelines regarding promotion). The FDA has enforced these requirements notwithstanding their ostensible "draft" status. *See, infra,* at p. 17.

19. For FDA warning letters concerning device promotion, *see* 2 W. Pines, *FDA Advertising & Promotion Manual* App. IV §C (Thompson Publishing Group 1995). These warning letters go well beyond device catalogues and brochures, and have imposed requirements upon: print and broadcast "advertising" (*id.* C-13, C-17, C-21, C-25, C-29, C-33, C-41, C-63, C-105, C-117, C-123, C-139, C-149, C-153, C-155, C-165, C-167, C-193, C-203, C-209); physician training seminars (C-3, C-39, C-53, C-67, C-89); letters to doctors (C-71, C-87, C-211); audiovisual materials (C-37, C-199); displays at medical conferences (C-85, C-135); reprints of medical literature (C-89); mail order sales literature (C-95); press releases (C-211); and even filings with the Securities and Exchange Commission (C-211).

design specifications. 21 C.F.R. §820.100(a). This requirement assures that the device being produced will continue to conform to its cleared "design specifications." 43 Fed. Reg. 31508, 31509 (FDA Jul. 21, 1978).[20]

Furthermore, design and labeling do not exist, and cannot be viewed, in isolation from one another. At any time after clearance, if a device design proves hazardous, the FDA can require addition of a warning or contraindication to the labeling. 21 C.F.R. §§803.3(g); 895.25(a-b). If the design hazard is too serious to be addressed through relabeling, the FDA can order a recall or can ban the device entirely. *See* 21 U.S.C. §§360f, 360h.

The FDA's post-market design requirements further establish that plaintiffs' design-related state-law tort claims are preempted.

C. FDA Enforcement Of Its Requirements

If it finds a medical device "adulterated" or "misbranded" for violating its requirements, the FDA has many enforcement options:

- detention without prior notice, 21 U.S.C. §334(g);
- seizure and forfeiture, *id.* §334(a)(2)(D);
- a permanent ban, *id.* §360f;
- injunctions against violations or further marketing, *id.* §332;
- felony (with proof of intent) or misdemeanor (not requiring proof of intent) criminal prosecution, *id.* §333(a);[21]

20. The FDA is now adopting "pre-production design validation," *21 U.S.C. §360j(f)(1)(A)*, requirements. *See* 58 Fed. Reg. 61952-86 (FDA Nov. 23, 1993) (describing proposed 21 C.F.R. §820.30), *mod.*, 60 Fed. Reg. 37856-58 (FDA Jul. 24, 1995). Final promulgation of §820.30 will subject the entire process of device design to formal FDA regulation.

21. In criminal cases, the Victim and Witness Protection Act also authorizes the FDA to seek a restitution order benefitting individuals harmed by a violation. *See* 18 U.S.C. §3663(a)(1).

- civil fines of up to $1,000,000, *id.* §333(f)(1)(A);
- mandatory device recall, *id.* §360h(e);
- an order requiring repair, replacement, or refund of the purchase price, *id.* §360h(b), and which may require reimbursement of third-party compliance expenses, *id.* §360h(c);
- an order requiring issuance of notice to the medical community and/or a patient safety alert, and/or a labeling change, *id.* §§352(a); 352(f)(1); 352(j); 360h(a);
- for a "minor violation," enforcement may be limited to written notice to the violator. *Id.* §336.[22]

Ongoing enforcement activity is another fertile source of FDA "requirements." For serious violations, such requirements may take the form of a court order. *See, e.g., United States v. C.R. Bard, Inc.*, 848 F. Supp. 287, 291-92 (D. Mass. 1994). Requirements are also enforced via FDA warning letters directed to both individual manufacturers and entire industries.[23] In particular, the FDA has enforced limitations on manufacturers' promotional activities even though its requirements (discussed, *supra*, at p. 15 n. 18) ostensibly remained in "draft" form. *See Washington Legal Foundation v. Kessler*, 880 F. Supp. 26, 34-35 (D.D.C. 1995) (detailing enforcement campaign).

FDA's comprehensive regulation of medical devices and the broad preemption of state law mandated by Congress are

22. For violations (minor or otherwise) discovered during FDA inspections, notice is provided by a Form 483. *See* 2 M. Heller, *Guide to Medical Device Regulation* App. IV at 7-8 (Thompson Publishing Group Oct. 1995) (sample form). For other minor violations, the violator receives a "warning letter."

23. FDA warning letters since 1990 are compiled at IHS® Regulatory Products, "The Medical Devices Library," Disc 1, *Regulation*, vol. 96-02 (CD-ROM). Absent prompt corrective action, FDA warning letters typically threaten sanctions "includ[ing], but [] not limited to injunction, seizure and/or civil penalties." *Id.*

two sides of the same coin. As Congress intended and anticipated, FDA "requirements" under the MDA go well beyond formal regulations, and all FDA "requirements" are preemptive, whether imposed by regulation, FDA guidance documents, FDA-obtained court orders, or enforcement through inspections and warning letters. 21 U.S.C. §360k(a). *See* M. Herrmann & G. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann,"* 51 Food & Drug L.J. 1, __ (1996) (forthcoming). In this case, FDA requirements pertain to every aspect of the Medtronic device challenged in plaintiffs' state-law complaint. Under the plain terms of §360k(a), all of plaintiffs' claims are expressly preempted.

III. Federal Preemption May Not Be Avoided By Basing State-Law Liability On Alleged Violations Of FDA Requirements.

Plaintiffs cannot render preemption ineffective by recasting their action as one for supposed violations of FDA requirements.[24] "[C]ompliance with the intent of Congress cannot be avoided by mere artful pleading." *Chicago and North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981). The Court of Appeals correctly stated that "preemption under the MDA cannot be defeated by a common-law suit alleging a violation of the statutory standards." *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1343 (11th Cir. 1995). Plaintiffs argue (for the first time) that claims raising regulatory violations escape preemption because applicable state-law requirements are "consistent" with FDA requirements. Pl. br. at 46. Assuming that this argument has not been waived, it fails for three independent reasons. First, the terms of §360k(a) are not susceptible to an implied exception for "consistent" state requirements. To the contrary, Congress deleted precisely that exception. Second, such claims contradict the basic structure of the FDCA, under which only the federal government may prosecute violations. Third, plaintiffs' basic premise is fallacious; neither state-law standards of liability nor state-law remedies could possibly be "consistent" with FDA requirements.

24. Plaintiffs admit that their tort claims "could easily" be converted to claims for regulatory violations. Pl. br. at 46.

A. *Consistent State Requirements Are Facially Preempted By §360k(a), And Congress Deleted Language Preserving Such Claims.*

Express preemption "begin[s] with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) (quoting *FMC Corp. v. Holliday*, 498 U.S. 52, 57 (1990)). Section 360k(a) "necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658, 664 (1993). It is phrased disjunctively: expressly preempting not only state requirements "different from" the FDA's requirements, but also those that are "in addition to" federal requirements — even if not "different." Had Congress intended to preserve congruent state requirements, it would have done so expressly, as it has done in many other statutes.[25]

In the MDA, precisely the opposite occurred. The scope of express preemption became broader as the MDA moved

25. *See* Poison Prevention Packaging Act, 15 U.S.C. §1476(a) (preempting state standards "not identical to the standard established under. . . this title") (emphasis added); Consumer Product Safety Act, 15 U.S.C. §2075(a) (preempting certain state requirements "unless such requirements are identical to the requirements of the Federal standard") (emphasis added); Toxic Substances Control Act, 15 U.S.C. §2617(a)(2)(B) (preempting state requirements "unless such requirement (i) is identical to the [federal] requirement") (emphasis added); Nutritional Labeling and Education Act, 21 U.S.C. §343-1(a)(1) (preempting any state standard "that is not identical to such [federal] standard") (emphasis added); Radiation Control for Health and Safety Act, 21 U.S.C. §360ss (preempting any state standard . . . applicable to the same aspect of performance of such product and which is not identical to the Federal Standard") (emphasis added); National Traffic and Motor Vehicle Safety Act, 49 U.S.C. §30103(b) ("a State or political subdivision of a State may prescribe or continue in effect a standard . . . only if the standard is identical to the standard prescribed under this chapter") (emphasis added).

through Congress. The original bills (1) limited preemption to two specified types of FDA regulations; (2) barred only state "standard[s] or regulation[s]" that "prescribe[d]. . .requirements" and "deal[t] with the same device" as the federal regulations; and (3) preserved state law where its "requirements are identical to the Federal requirements."[26] When S. 510 — the bill that eventually became the MDA — passed the Senate on April 17, 1975, it provided:

> Sec. 903. (a) Whenever a performance standard pursuant to section 513 or scientific review pursuant to section 514 under this Act is in effect, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the Federal requirements.

94th Cong., 1st Sess. at 73-74 (1975) (emphasis added) (reproduced in Appendix "E"). *See* 121 Cong. Rec. 10688, 10709-10 (S. Apr. 17, 1975).

The preemption language now in 21 U.S.C. §360k(a) arose in the House of Representatives.[27] The House substituted that language for what was in S. 510 and passed the bill on March 9, 1976. 122 Cong. Rec. 5848 (H.R. Mar. 9, 1976). A conference committee agreed to the House amendments. *See* H. Conf. Rep. No. 1090, 94th Cong., 2d Sess. 51 (1976) (reprinted at 1976 U.S.C.C.A.N. 1070, 1103).[28]

26. *See* H.R. 9984, 93d Cong., 1st Sess. §903(a) at 63 (1973); S. 2368, 93d Cong., 2d Sess. §903(a) at 73-74 (1974); S. 2697, 94th Cong., 1st Sess. §608(a) at 170-71 (1975). Appendix "E" reproduces the preemption provisions of all legislative precursors to the MDA between 1973 and the statute's enactment in 1976.

27. *See* H.R. 5545, 94th Cong., 1st Sess. §521(a) at 74-75 (1975); H.R. 11124, 94th Cong., 2d Sess. §521(a) at 87 (1976) (reproduced in App. "E").

28. The House preemption language passed both houses of Congress on May 13, 1976, and was signed into law on May 28, 1976. 122 Cong. Rec. 13777 (H.R. May 13, 1976); 122 Cong. Rec. 14005 (S. May 13, 1976); Pub. L. No. 94-295, 90 Stat. 539.

The explicit congressional rejection of narrow preemption in favor of the broad "different from or in addition to" language of §360k(a) defeats plaintiffs' contention that Congress silently intended to preserve "consistent" state law. To imply an exception for "consistent" state requirements would reverse the legislative process by which §360k(a) was enacted — restoring by judicial fiat the very exemption that Congress deleted from the statute. "Where Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended." *Russello v. United States*, 464 U.S. 16, 23-24 (1983). "[W]e are mindful that Congress had before it, but failed to pass, just such a scheme. . . . We are directed by th[e] words [of the statute], and not by the discarded draft." *John Hancock Mutual Life Insurance Co. v. Harris Trust & Savings Bank*, 114 S. Ct. 517, 526 (1993) (citation omitted). *Accord Morales*, 504 U.S. at 386 n.2 ("[i]t also bears mention that the rejected Senate bill did contain language that would have produced precisely the result the dissent desires").[29]

Moreover, plaintiffs' "consistent requirements" argument meets only the "different from" prong of MDA preemption. They cannot read the alternative basis for preemption — "or in addition to" — out of §360k(a)(1). The "ordinary meaning," *Morales, supra*, of "in addition to" is neither unclear nor obscure. For example, any car owner knows that a second coat of car wax is "in addition to" the first coat although the wax is the same. The second coat takes "additional" time and effort to apply. Analogously, §360k(a)(1) precludes the "addition" of a second layer of legal scrutiny, consisting of state require-

29. The argument that only FDA regulations are preemptive meets the same fate. Where Congress meant to specify "regulations" in §360k, it did so. *See* 21 U.S.C. §360k(b) (a preemption exemption requires an FDA "regulation"). The term requirement in §360k(a) replaced less expansive language that would have preempted only a state "standard or regulation which prescribes . . . requirements." *Compare, e.g.*, H.R. 9984 §903(a) (introduced Aug. 3, 1973); S. 510 §903(a) (passed Senate Apr. 17, 1975), *with*, H.R. 11124 §521(a) (*see* App. "E"); 21 U.S.C. §360k(a).

ments "applicable" to medical devices. It eliminates duplication and prevents state courts and juries from second-guessing FDA regulatory and prosecutorial decisions. And it bars imposition of a burdensome set of overlapping requirements of the sort that Congress believed would stifle innovation by small device manufacturers.[30]

Plaintiffs also ignore §360k(a)(2). Congress broadened its scope as well — from the precursor bills' preemption only of state law "deal[ing] with the same device" to the statute's preemption of any state law that "relates to" either "safety or effectiveness" or "any other matter included in a [federal] requirement." This evolution of §360k(a) "indicat[es] that the section's pre-emptive scope was as broad as its language." *FMC*, 498 U.S. at 59 (quoting *Shaw v. Delta Air Lines*, 463 U.S. 85, 98 (1983)). "Relates to" preemption language has repeatedly been recognized by this Court as "deliberately expansive." *District of Columbia v. Greater Washington Board of Trade*, 506 U.S. 125, 129 (1992); *Morales*, 504 U.S. at 383; *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. 41, 46 (1987). Where all state law that "relates to" a particular topic is preempted, nothing is left, not even "consistent" state requirements:

> Nothing in [the statute] suggests that its "relating to" pre-emption is limited to inconsistent state regulation; and once again our ERISA cases have settled the matter: "The pre-emption provision . . . displace[s] all state laws that fall within its sphere, even including state laws that are consistent with ERISA's substantive requirements."

Morales, 504 U.S. at 387 (quoting *Mackey v. Lanier Collection Agency & Service, Inc.*, 486 U.S. 825, 829 (1988)).

Plaintiffs admit that they are basing state tort liability "by reference to [the] federal standard." Pl. br. at 45. Express pre-

30. *See, e.g., Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995), *cert. pending*, 64 U.S.L.W. 3593 (U.S. filed Feb. 16, 1996); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995); *Reeves v. AcroMed Corp.*, 44 F.3d 300, 307 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995).

emption of all claims "relating to" such federal standards defeats that effort. Absent the federal requirement, there can be no claim for its violation. Litigation asserting a regulatory breach necessarily "relates to" the allegedly violated requirement, and is therefore preempted. *See Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 140 (1990) (state tort claim preempted as "relating to" an ERISA plan because "there simply is no cause of action if there is no plan"). Such claims must yield to the MDA's express preemption of all state law "relat-[ing] to . . . matte:[s] included in a[n MDA] requirement." 21 U.S.C. §360k(a)(2).

Finally, an implied exemption for "consistent" state requirements would also render superfluous 21 U.S.C. §360k(b)(2)(B), which allows the FDA to preserve from pre-emption state-law requirements "compliance with [which] would not cause the device to be in violation of any applicable [federal] requirement." If identical state standards were already outside §360k(a), then the exemption in §360k(b)(2)(B) has no function. *See Morales*, 504 U.S. at 386 (rejecting narrow construction of "relates to" preemption clause that left "no purpose" to be served by an express statutory exception to preemption).

B. *Exempting "Consistent" State Requirements From Pre-emption Would Violate The Exclusive Enforcement Authority Of The FDA.*

Literal application of the broad preemption language that Congress added to §360k(a) — barring duplicative state-law enforcement of the MDA — is also consistent with the basic structure of the FDCA. *See Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 98 (1992) ("Our ultimate task in any pre-emption case is to determine whether state regulation is consistent with the structure and purpose of the statute as a whole.") (plurality opinion). The MDA and the FDCA as a whole do not allow private rights of action, so these plaintiffs cannot act for the FDA. Only the FDA (with the Department of Justice) may enforce the FDCA and the MDA:

> all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

21 U.S.C. §337(a).[31]

This Court has "assume[d]" that private plaintiffs may not seek enforcement of the FDCA. *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 810 (1986). It "would flout congressional intent" to allow either an implied private FDCA cause of action or state-law actions with FDCA violations as a "rebuttable presumption" or a "proximate cause." *Id.* at 812. Lower courts have unaniously barred private suits for violations of the FDCA or MDA.[32]

Congress tempered enforcement of the FDCA and the MDA by granting prosecutorial discretion to the FDA:

> Nothing in this chapter shall be construed as requiring the [FDA] to report for prosecution . . . minor violations of this chapter whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning.

21 U.S.C. §336. "The Act's enforcement provisions . . . commit complete discretion to [the FDA] to decide how and when they should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). This discretion is "broad enough undoubtedly to

31. Before the FDCA was enacted, a provision granting a private right of action "for injury or death proximately caused by a violation of this Act" was deleted. S. 1944, 73d Cong., 1st Sess. §24 (1933) (reprinted in C.W. Dunn, *Federal Food, Drug, and Cosmetic Act, A Statement of Its Legislative Record* at 49 (G.E. Stechert 1938). *See, supra*, at p. 21.

32. *E.g., Talbott*, 63 F.3d at 30-31; *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995); *Michael*, 46 F.3d at 1329; *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 19 n.4 (1st Cir. 1994); *Rodriguez v. SK & F Co.*, 833 F.2d 8, 9 (1st Cir. 1987); *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, 766 F.2d 1005, 1006 (6th Cir. 1985), *aff'd on other grounds*, 478 U.S. 804 (1986); *Fiedler v. Clark*, 714 F.2d 77, 79 (9th Cir. 1983); *Gelley v. Astra Pharmaceutical Products, Inc.*, 610 F.2d 558, 562-63 (8th Cir. 1979); *Pacific Trading Co. v. Wilson & Co.*, 547 F.2d 367, 370 (7th Cir. 1976).

enable [the FDA] to perform [its] duties fairly without wasting [its] efforts on what may be no more than technical infractions of law." *United States v. Sullivan*, 332 U.S. 689, 694 (1948).

If the FDA chooses to prosecute a violation, it has many enforcement tools. *See, supra*, at pp. 16-18. But under §336, the FDA also may treat a violation as "minor" and act accordingly. Indeed, this is how the FDA handles most violations, particularly of GMPs — by voluntary manufacturer compliance. *FDA Enforcement Manual* ¶403 at 6. The spectre of private tort liability would only disrupt voluntary compliance by forcing manufacturers to contest many of the FDA's thousands of findings of minor deficiencies. *See, supra*, at 13 n. 15. To exempt any tort claim asserting a regulatory violation from preemption would give minor regulatory violations a significance that neither Congress nor the FDA intended.

Even more destructive is the situation here, where plaintiffs seek to litigate supposed regulatory violations that the FDA has neither found to exist nor sought to pursue. Allowance of such claims would completely divest the FDA of its prosecutorial discretion. The Agency would lose control, not only of remedies, but even of its ability to determine whether or not there has even been a violation. If that discretion were eliminated, "the major advantages of enforcement through the Secretary would be lost," such as "expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a unitary enforcement policy." *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995) (citation and quotation marks omitted).

The State of Florida cannot "use the threat of damages to require [a defendant] to do exactly what the [FDA] is empowered to excuse." *Chicago and NW*, 450 U.S. at 326. The MDA does not contemplate "a dual system of futile duplication of two authorities over the same subject matter." *California v. Federal Energy Regulatory Commission*, 495 U.S. 490, 502 (1990) (citation and quotation marks omitted). Preemption maintains both the FDA's exclusive enforcement authority and its prosecutorial discretion. Because §360k(a) codifies congres-

sional intent that FDA oversight be the sole avenue for adjudication of regulatory violations by medical device manufacturers, most courts of appeals have agreed with the Eleventh Circuit in this case and have held such claims preempted as little more than disguised private rights of action.[33]

As in *Chicago and NW,* only the FDA "has the power to declare [an act] unlawful" under the MDA. 450 U.S. at 324. State-law claims asserting violations of FDA requirements at best duplicate and at worst second-guess the FDA. Tort liability in this case would be a sanction (1) that the FDA has not imposed (2) for conduct the FDA has never found violative of its requirements. Such liability would be — inherently and necessarily — a state-law "requirement" that is "different from, or in addition to" the requirements enforced by the FDA under the MDA.

33. *See Talbott,* 63 F.3d at 29 ([n]othing in §360k(a) suggests that the state requirements are somehow revived by this failure to comply with the federal standard"); *Michael,* 46 F.3d at 1329 ("[u]nder the MDA, states have no authority to police. . .compliance with the FDA's procedures. . . . [I]t is for the FDA to remedy that situation using the authority Congress gave it"); *Reeves,* 44 F.3d at 307 ("[a]llowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress' expressly stated intent"); *Gile,* 22 F.3d at 544 (a plaintiff "cannot overcome a finding of preemption merely by claiming that the product was adulterated"); *Mendes,* 18 F.3d at 19 n.4 ("find[ing] nothing to support that Congress intended such a radical, unwieldy form of preemption . . . particularly where Congress did not intend to create a private right of action").

Accord, e.g., Duke v. American Medical Systems, Inc., 1995 WL 505472, slip op. at *5 (N.D. Ill. Aug. 18, 1995); *Chadwell v. Optical Radiation Corp.,* 902 F. Supp. 830, 836 (S.D. Ind. 1995); *Fender v. Medtronic, Inc.,* 887 F. Supp. 1326, 1332 (E.D. Cal. 1995); *Petix v. Kabi Pharmacia Ophthalmics, Inc.,* 884 F. Supp. 92, 99 (W.D.N.Y. 1995); *Richman v. W.L. Gore & Associates, Inc.,* 881 F. Supp. 895, 902 (S.D.N.Y. 1995); *Kemp v. Pfizer, Inc.,* 835 F. Supp. 1015, 1022 (E.D. Mich. 1993); *Scott v. Ciba Vision Corp.,* 44 Cal. Rptr. 2d 902, 911-12 (Cal. App. 1995); *Niehoff v. Surgidev Corp.,* 1995 WL 794203, slip op. at *7 (Ky. App. Nov. 17, 1995); *Mears v. Marshall,* 905 P.2d 1154, 1166-68 (Or. App. 1995); *Green v. Dolsky,* 641 A.2d 600, 606 (Pa. Super.), *appeal granted,* 652 A.2d 1324 (Pa. 1994).

C. *State-Law Non-Compliance Claims Cannot Possibly Impose Requirements Consistent With The FDA's Requirements.*

Finally, plaintiffs' facile contention that the common law of fifty states can somehow yield results "consistent" with the FDA's requirements cannot withstand analysis. Courts are "not bound by the name, description or characterization" of state law, "but will determine for [themselves] the practical impact of the law." *Hughes v. Oklahoma,* 441 U.S. 322, 336 (1979) (citation and quotation marks omitted). Common law actions would necessarily give varying and conflicting meanings to FDA requirements, particularly where, as here, the FDA has never identified and never pursued the alleged regulatory violation. The disparate judicial constructions given to 21 C.F.R. §808.1, the FDA's explication of 21 U.S.C. §360k(a), only reinforce this common-sense conclusion.[34] Those differences would multiply a thousand-fold if all FDA substantive requirements were open to competing interpretations by state-law tort litigants.

State courts and juries cannot possibly duplicate FDA interpretation and enforcement of the MDA. Every contested case would necessarily involve at least two opposing constructions of relevant FDA requirements. At least one interpretation — and quite often both (or all) of them — would not be consistent with the FDA's reading. No court or jury could unerringly pick the FDA's "correct" interpretation, even assuming that interpretation were before it. They should not be asked to undertake that impossible task.

34. *Compare Kennedy v. Collagen Corp.,* 67 F.3d 1453, 1459 (9th Cir. 1995) (§808.1 eliminates preemption of state-law tort claims), *with, Lohr,* 56 F.3d at 1345 (§808.1 allows preemption of tort claims), *with, English v. Mentor Corp.,* 67 F.3d 477, 483 (3d Cir. 1995) (§808.1 allows preemption of tort claims; if not, it would conflict with §360k(a) and be void), *cert. pending,* 64 U.S.L.W. 3469 (U.S. filed Dec. 26, 1995), *with, Duvall v. Bristol-Myers-Squibb Co.,* 65 F.3d 392, 398 (4th Cir. 1995) (§808.1 would eliminate preemption of tort claims, but conflicts with §360k(a) and is void), *cert. pending,* 64 U.S.L.W. 3439 (U.S. filed Dec. 22, 1995), *with,* 45 Fed. Reg. 67321, 67323 (FDA Oct. 10, 1980) (§808.1 allows preemption from the moment that the FDA applies a requirement to a device).

— Thus, even if state tort law were ostensibly applying the FDA's own requirements, in practice that identity could not be maintained. The parties — supported by antagonistic "regulatory experts"[35] — would dispute what the FDA's requirements are. The FDA recognizes preemption in this situation:

> In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language . . ., which may be identical to a provision in the act.

See 21 C.F.R. §808.1(d)(6)(ii) (preemption of state requirements respecting adulterated or misbranded devices"). The same reasoning bars state common law claims asserting regulatory violations. Preemption bars state law that purports to adopt FDA requirements because, in practice, disparate "interpret[ation] and enforce[ment]" *id.*, is inevitable.[36]

Available remedies are also dissimilar. Plaintiffs seek substantial damages for alleged violations the FDA has never found to exist. Not even the FDA can seek that remedy in a

35. The proof required by such litigation could well perniciously affect the FDA. At best, the Agency would be processing many litigation-inspired Freedom of Information Act requests, and retiring Agency personnel (shielded from private process during their tenure) would be subpoenaed for their knowledge of FDA regulatory activity involving any number of devices. Internal Agency disputes could become fodder for litigation, as the participants left the FDA to become highly compensated "regulatory experts" for opposing litigants. At worst, the future prospect of lucrative litigation-related employment could influence regulators' actions while still at the FDA.

36. *See* Talbott, 63 F.3d at 29:

> [W]e need only imagine how such an exception [to preemption] would operate in practice. If state tort claims were allowed to go forward, a state court would initially have to determine whether the manufacturer had complied with the MDA. . . . Under this scheme, a device manufacturer could potentially be subject to numerous inconsistent interpretations and applications of the MDA across different states, thus undermining the MDA's goal of uniformity.

civil case.[37] Money damages are both different from and in addition to the sanctions and remedies provided in the MDA and, as such, are preempted:

> We think it would . . . flout, or at least undermine, congressional intent to . . . provide remedies for violations of that federal statute [the FDCA] solely because the violation of the federal statute is said to be a rebuttable presumption or a proximate cause under state law. . . .

Merrell Dow, 478 U.S. at 812 (footnote omitted). To allow a private plaintiff a remedy for an MDA violation that is denied even to the FDA would ignore the policy choices made by Congress:

> [T]he policy choices reflected in the inclusion of certain remedies and the exclusion of others under the federal scheme would be completely undermined if [plaintiffs] were free to obtain remedies under state law that Congress rejected. . . .

Metropolitan Life Insurance Co. v. Taylor, 481 U.S. 58, 64-65 (1987) (quoting *Pilot Life,* 481 U.S. at 54).

Both the terms of 21 U.S.C. §360k(a) and its legislative history demonstrate that Congress did not intend to preserve state-law non-compliance claims from preemption. This Court should not create by implication an exception that Congress expressly deleted from §360k(a).

37. Only in criminal cases, with a higher burden of proof, can the FDA seek restitution for persons injured by violations of its requirements. *See,* supra, pp. 16-17 n. 21. Congress need not "duplicate the recovery at common law or provide a reasonable substitute remedy" when it preempts the common law. *Duke Power Co. v. Carolina Environmental Study Group, Inc.,* 438 U.S. 59, 88 (1978) (footnote omitted). *Accord Martin v. Telectronics Pacing Systems, Inc.,* 70 F.3d 39, 42 (6th Cir. 1995), *cert. pending,* 64 U.S.L.W. 3593 (U.S. filed Feb. 20, 1996).

CONCLUSION

For all of the above reasons, the judgment of the United States Court of Appeals for the Eleventh Circuit should be affirmed in part and reversed in part, with all of plaintiffs' state-law claims being dismissed as expressly preempted by the Medical Device Amendments to the Federal Food, Drug & Cosmetic Act.

Respectfully submitted,

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GUIDANCE ON THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH'S PREMARKET NOTIFICATION REVIEW PROGRAM
(June 30, 1986)

PURPOSE OF THE GUIDANCE

This guidance document outlines requirements for premarket notification review, and explains some points the Center for Devices and Radiological Health (CDRH) will consider when making a determination that a device is, or is not, "substantially equivalent." A consistent application of the principles set forth in the guidance should be useful to Center staff in conducting complete and expeditious reviews of 510(k) submissions.

PURPOSE OF THE PROGRAM

In brief, the premarket notification program is meant to:

- identify new devices that must be placed automatically into class III and undergo premarket approval or reclassification before they are marketed;
- classify new devices; a not substantially equivalent (NSE) new device is in class III, and a substantially equivalent (SE) new device is in the same regulatory class as the device to which it is found equivalent; and
- achieve marketing equity by allowing manufacturers of new devices that are SE to pre-Amendments devices to market their devices without facing any greater regulatory burdens than faced by manufacturers of the pre-Amendments devices.

BACKGROUND

THE STATUTE: The Medical Device Amendments were enacted on May 28, 1976. They direct FDA to issue regulations that classify all devices that were in commercial distribution at that time into one of three regulatory control categories, class I, II, or III, depending upon the degree of regulation necessary to provide reasonable assurance of their safety and effectiveness. The class into which a device is

placed determines the requirements that must be met before a manufacturer may distribute the device in interstate commerce.

Class I devices are subject to a comprehensive set of regulatory authorities applicable to all classes of devices, e.g., premarket notification, registration and listing, prohibitions against adulteration and misbranding, and rules for good manufacturing practices. Class II devices also need performance standards, and class III devices need premarket approval.

The Act also specifies how a new device, i.e., a post-Amendments device, is to be classified. A post-Amendments device is automatically in class III and must undergo premarket approval or reclassification before it can be marketed, unless it is within a type of device that was in commercial distribution prior to May 28, 1976 and is SE to another device within such type; or, it is within a type of device introduced after May 28, 1976 that has been reclassified into class I or II and is SE to another device within such type. A SE device is in the same class, and is subject to the same requirements, as the device to which it is SE.

Section 510(k) of the Act requires a person who wishes to introduce a device into commerce to notify the Center at least ninety days in advance. This premarket notification is referred to as a "510(k)." The Agency uses 510(k)s to determine if new devices are, or are not, SE to either a pre-Amendments device or a reclassified post-Amendments device.

CONGRESSIONAL GUIDANCE: The statutory objectives for the 510(k) program are clear. Also, the Report by the Committee on Interstate and Foreign Commerce on the Medical Device Amendments of 1976 (House Report) offers some additional guidance on program implementation, describing the term "substantial equivalence" as follows:

> The term "substantially equivalent" is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The committee believes that the term

> should be construed narrowly where necessary to assure the safety and effectiveness of a device but not narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness. Thus, differences between "new" and marketed devices in materials, design, or energy source, for example, would have a baring [*sic*] on the adequacy of information as to a new device's safety and effectiveness, and such devices should be automatically classified into class III. On the other hand, copies of devices marketed prior to enactment, or devices whose variations are immaterial to safety and effectiveness would not necessarily fall under the automatic classification scheme.[1]

If substantial equivalence were judged too narrowly, the marketing of devices that would benefit the public would be delayed; the device industry would be unnecessarily exposed to the greater burdens of premarket approval; new devices would not be properly classified; and new manufacturers of pre-Amendments type devices would not have marketing equity. If substantial equivalence were judged too broadly, the statutory purpose may not be served, i.e., devices with new uses or those presenting new or different risks would be marketed without adequate regulatory control.

THE 510(K) REGULATION: On August 23, 1977, FDA issued a final regulation for Establishment Registration and Device Listing for Manufacturers of Devices (21 CFR Part 807). Subpart E describes premarket notification procedures. The 510(k) rules were incorporated into the registration and listing regulation because the 510(k) requirements apply only to those persons required to register.

The regulation describes the circumstances under which a 510(k) must be submitted, the information required, and the FDA rules for maintaining confidentiality of submitted infor-

1. H.R. Rep. No. 94-853 pp. 36-37. The Amendments, as enacted, are comprised primarily of the bill H.R. 11124 as drafted by the Subcommittee on Health and the environment of the Committee on Interstate and Foreign Commerce and adopted by the House of Representatives. This report provides the only Congressional guidance on the criteria for substantial equivalence.

mation. Essentially, the regulation provides that a person required to register must submit a 510(k) at least ninety days before marketing a device that: (1) is being introduced into distribution for the first time by that person, or (2) is in distribution but is being significantly modified in design, or use, etc.[2]

A 510(k) must contain, among other things:

- proposed labeling sufficient to describe the device's intended use;
- a description of how the device is similar to or different from other devices of comparable type, or information about what consequences a proposed device modification may have on the device's safety and effectiveness; and
- any other information the Center needs to determine whether the device is SE

The statute provides that a new device can be SE to one of two type of devices (from hereon referred to as a "predicate device"). A predicate device is one that was in distribution prior to enactment of the Amendments, or it is a post-Amendments device that was subject to reclassification from class III to class I or II. The Center does not routinely require that manufacturers perform research to determine what specific predicate devices a [*sic*] were available in 1976, or were available at the time a post-Amendments device was reclassified from class III to class I or II; nor does the Center routinely require that all 510(k)s initially provide information on a predicate device. Instead, the Center requires submitters to provide information that compares the new device to a marketed device of similar type, regardless of whether this marketed device was marketed before or after enactment of the Amendments, or before or after a type of post-Amendments device was reclassified.

This means that the manufacturer can submit a 510(k) comparing a new device to a device that has been found to be

2. This document does not provide guidance on what changes in marketed devices are significant enough to require the submission of a 510(k), but the Center plans to issue such guidance in the near future.

SE. It does not mean, however, that the Center finds new devices SE to devices that have been found SE. It only reflects the agency's position that the similarity of a new device to a marketed device is evidence that can be considered in determining that the new device is, as is the marketed device to which it is compared, SE to a predicate device. Nevertheless, the ultimate burden of demonstrating the substantial equivalence of a new device to a predicate device remains with the 510(k) submitter, and in those occasions when the Center is unfamiliar with certain aspects of the predicate device, the submitter will be required to provide information that substantiates a claim of substantial equivalence.

The guidance that follows assumes that 510(k)s provide comparisons with marketed devices.

GENERAL POINTS CONSIDERED BY CDRH DURING THE REVIEW OF 510(K) SUBMISSIONS

CDRH normally approaches the review of 510(k)s by considering the following points:

> Does the new device have the same intended use as a predicate device? Does the new device have the same technological characteristics, i.e., same materials, design, energy source, etc.? If it has new technological characteristics, could they affect safety or effectiveness?

If the new device has a new intended use (what constitutes a new intended use is discussed below), it is considered NSE. If the new device has the same intended use as a predicate device and the same technological characteristics related to safety and effectiveness, the new device is considered SE. If the new device has the same intended use as a predicate device, and it has new technological features that could affect safety or effectiveness, additional issues are considered:

> Do the new technological features pose the same type of questions about safety or effectiveness as are posed by the predicate device with the same intended use? Are there accepted scientific methods for evaluation whether safety or effectiveness has been adversely affected as a result of the use of new technological characteristics? Is

there information to demonstrate that the new technological features have not diminished safety and effectiveness?

If the answers to any of the above questions are negative, the device is generally considered NSE.

Thus, as a matter of practice, CDRH generally considers a device to be SE to a predicate device if, in comparison to the predicate device:

- the new device has the same intended use (as discussed below); and,
- the new device has the same technological characteristics, (i.e., same materials, design, energy source, etc.); or, it has new technological characteristics that could not affect safety or effectiveness; or
- it has new technological characteristics that could affect safety or effectiveness, and
  - — it generates the same type or [*sic*] questions about safety or effectiveness:
  - — there are accepted scientific methods for evaluating whether safety or effectiveness has been adversely affected as a result of the use of new technological characteristics; and
  - — there are data to demonstrate that the new technological features have not diminished safety or effectiveness.

Premarket notification submissions should be designed to answer these questions. The guidance below describes how the Center draws conclusions about the questions. The guidance covers the meaning of "intended use," technological changes that can be reviewed under the 510(k) process, data that are required in a 510(k), and what "combination" devices can be 510(k)'ed. Also, flow charts on Attachments I and II illustrate the decision making process.

THE MEANING OF INTENDED USE

While a new device must have the same intended use as a predicate device in order to be SE, the Center does not require that a new device be labeled with precise therapeutic

or diagnostic statements identical to those that appear on predicate device labeling in order for the new device to have the same intended use. Label statements may vary. Certain elements of a predicate device's labeled indication may not be critical to its intended therapeutic, diagnostic, prosthetic, surgical, etc., use. The Center's scientific expertise enables it to exercise considerable discretion in construing intended uses in the labeling and promotional materials for predicate and new devices.[3] Thus, a new device with the same intended use as a predicate device may have different specific indication statements, and, as long as these label indications do not introduce questions about safety or effectiveness different from those that were posed by the predicate device's intended use, the new device may be found SE.

For the purposes of determining whether or not the new device has the same intended use as a predicate device, the Center assesses any differences in label indications in terms of the safety and effectiveness questions they may raise. The Center considers such points as physiological purpose (e.g. removes water from blood, transports blood, cuts tissue), condition or disease to be treated or diagnosed, professional or lay use, parts of the body or types of tissue involved, frequency of use, etc. If a new device is determined to have the same intended use, the Center may then proceed to determine whether or not it is substantially equivalent. (Devices which do not have the same intended use cannot be substantially equivalent.) The following examples illustrate these concepts.

> Nonimplanted Blood Access Device: This type of pre-Amendments class II device is intended to provide access to a patient's blood so that blood can, for example, be subjected to hemodialysis. Pre-1976 devices are labeled for insertion into the femoral vein. New devices that are labeled for insertion into the subclavian vein may have the same intended use to the extent that labeling for the new and predicate devices indicates that both are

3. Ordinarily, intended use is determined by reference to "labeling" or promotional claims; only in rare cases might it be necessary to infer intended use from other types of information.

intended to provide access to a patient's blood for similar purposes. The differences in labeling described above do not undercut the fact that the new and predicate devices have the same intended use. CDRH was further able to conclude that, because the differences in labeling related only to a method of use not relevant to the effect that the insertion is to achieve (and therefore did not pose new safety or effectiveness questions) and because there were not other significant changes (in technology, design, etc.), the new device was substantially equivalent.

Conventional Dialyzer: This type of pre-Amendments device is in class II. The pre-Amendments devices are labeled for use as part of artificial kidney system for patients with renal failure. The principal purpose of the device is to remove excess water from the vascular system. Some new devices that have been found SE are labeled for use as part of a heart-lung machine to remove excess water from the vascular system at the end of surgery. Again, the Center concluded that this is not a different intended use. Differences in the labeling relate only to a nonessential condition that does not bear materially on the safe and effective use of the device, and moreover, there are no other significant changes (in technology, design, etc.); therefor, the devices are substantially equivalent.

Blood Tubing Set: This pre-Amendment class II device consists of tubing that enable blood to flow from a patient to a dialyzer and back to the patient. Some new devices that have been found SE are labeled for use in carrying blood to and from a plasmapheresis device. The Center concluded that this is not a different use for the two tubings.

The labeling differences relating to the subclavian catheter, the conventional dialyzer for use with the heart-lung machine, and the blood tubing set for plasmapheresis, are not significant enough to require a finding that the devices are for different intended uses. Moreover, the specific uses associated with the labeling modifications do not present issues of safety

and effectiveness different from those posed by the use of their predicate devices, and therefore, the devices can be found SE in terms of intended use. On the other hand, for some new devices, modifications in label indications will not be found to represent the same intended use as a predicate device, even though the intended effect of the new device is very similar to that of the predicate device. This is because slight modifications in intended use can be significant to the claimed effect or purpose of the predicate device. If a device has a different intended use, there is no reason to proceed further to decide whether the devices are substantially equivalent. (Obviously, however, some of the same issues relevant to substantial equivalence determinations may arise in assessing whether or not devices are for the same intended use, i.e., differences in labeling are judged in terms of any safety and effectiveness questions they may raise.) Two examples follow:

Long-term Percutaneous Intravasular [*sic*] Catheter: This pre-Amendments, unclassified device consists of a slender tube labeled for insertion into the vascular system for extended periods in order to sample blood, monitor blood pressure, or administer drugs. A similarly designed device has been found NSE because it is labeled for use as a spinal canal access catheter. The new device was intended to deliver drugs over an extended period of time to the spinal canal. While both devices deliver drugs into the human body, each device relates to a different body system. The concern raised by this difference led to the conclusion that the intended uses of the devices are not the same. Inserting the device into, and maintaining it in, the spinal canal raises significantly different safety issues compared to the issues posed by intravascular insertion; namely, the new device potentially posed risks to the spinal cord, whereas the predicate device did not.

Powered Aspirators: These pre-Amendments devices, currently proposed for class II, were labeled to remove loose bone chips, blood, or tissue from the body during surgery. Similarly designed new devices have been found NSE when labeled for use in "suction lipectomy." In this

new surgical procedure, the aspirating device is inserted under the skin to remove body fat, sometimes very large amounts of body fat, for cosmetic purposes. In suction lipectomy, the aspiration process performed by the device becomes the surgical procedure. It is no longer an aspirator merely used as an aid in performing another surgical procedure that is not aimed solely at the removal of fat. For these reasons, the new devices, as labeled, do not have the same intended uses as the predicate device. The difference in intended use is underscored by the fact that removal of large amounts of body fat through aspiration raises questions of safety and effectiveness not posed by the labeled use of pre-Amendments aspirators, e.g., possible metabolic changes, and permanent bagging of the skin resulting when the fat removed from the area exceed the ability of the skin to contract. Thus, the intended uses are not the same.

As the examples above illustrate, for a device to be found SE, it is important that a 510(k) for the device demonstrate that the intended use of the device does not differ from the intended use of marketed devices within the same type and that any changes in labeling are immaterial in terms of safety and effectiveness issues.

DEVICES WITH NEW TECHNOLOGICAL FEATURES

If a new device has the same intended use as a predicate device, and there are no technological differences between the new and a predicate device, the new device is SE. If the device has the same intended use and technological differences, but the technological differences could not affect safety or effectiveness, it is SE. If the device has the same intended use and technological differences that could affect safety or effectiveness, the new device may not be SE. Technological deferences may include modifications in design, materials, or energy sources; for example, changes in the power-levels of electrical surgical instruments, the use of new reagents in *in vitro* diagnostic devices, the use of new materials in orthopedic implants, and the use of new battery designs in implanted pacemakers. The Center finds devices with new technological

features to be NSE when the new feature could adversely affect safety or effectiveness in a way that is consequential under the conditions of intended use.

In taking this approach, the Center focuses on the technological differences that are medically and scientifically significant and avoids the difficulties that would arise from a mechanistic application of rigid formal criteria to the wide variety of substantial equivalence questions posed by new devices proposed for marketing under a 510(k). Substantial equivalence determinations of necessity require the Center to exercise reasonable scientific judgment. For example, the strict application of a rule that would make devices NSE if they have a new material would be inappropriate for such devices as bed pans. For other devices, a "materials rule" may seem more appropriate, e.g. for implants. Even for implants, however, such a rule would be too encompassing if applied to substitute materials known to be, or easily shown to be, equivalent or superior; for example, if applied to a new post-Amendments hip made of titanium, which is generally known to be, and can easily be shown to be, stronger and less corrosive that some stainless steel that was used in pre-Amendments hips.

Thus, from a scientific perspective, to determine which technological changes are consequential, the Center considers whether:

- The new device poses the same type of questions about safety or effectiveness as a predicate device.;
- there are accepted scientific methods for evaluating whether safety or effectiveness has been adversely affected as a result of the use of new technological characteristics; and
- there are data to demonstrate that new technological characteristics have not diminished safety or effectiveness.

The examples below should help clarify these concepts.

Electrocardiographs: This device is in class II. Pre-Amendments electrocardiographs produce an analog visual display of the electrical signals produced by the

heart. Some post-Amendments devices that have been found SE display these signals in a digital, rather than analog, form.

This technological innovation could affect the effectiveness of the device, i.e., the electronic components used to produce the digital display might not achieve the accuracy of an analog display. The Center found the new devices SE because the modification presented the same question of effectiveness as posed by the predicate device, i.e., does the display accurately represent the electrical activity of the heart. Also, there are accepted bench test procedures to demonstrate comparability of accuracy between the new and predicate devices, and the necessary comparability information was presented in the 510(k).

Inflatable Penile Implant: This device is in class III. The pre-Amendments implants consist of inflatable cylinders implanted in the penis, connected a a [*sic*] reservoir filled with fluid and implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. When the cylinders are inflated, they provide rigidity to the penis. The connections between the various parts of this system sometimes leaked. Manufacturers of post-Amendments versions of these devices modified the connector designs. These new devices have been found SE even though such a change would affect safety and effectiveness. This is because the new connectors presented the same questions of safety and effectiveness as posed by the predicate device, i.e., are the connector materials nontoxic and do the connectors leak? Since the material [*sic*] were the same, questions about the comparability of toxicity were obviated, and bench testing and clinical evidence easily and clearly demonstrated that the modified connectors were not more prone to leaks then the connectors in the predicate devices.

Perimeter: This device is proposed for classification in class I or II, depending on whether it is manually or electrically operated. The pre-Amendments devices are AC-powered or manual devices that project light on various points of a curved surface, and the patient manually indicates whether he or she sees the light. The devices are designed to determine the extent of a patient's peripheral vision. Manufacturers of post-Amendments devices have incorporated software into the device. The software automatically lights various points on the curved surface, and keeps track of whether the patient indicates that the light has been seen by recording that the patient has or has not pressed a button. The new device posed the same safety and effectiveness questions as the predicate devices, i.e., are the light-point in the appropriate places, is there risk of shock, do the points light up when they are meant to, and can the patient's reaction be accurately recorded. Because the questions are the same, and obviously accepted testing procedures can ensure comparability of performance between the new and predicate device, and because clinical data showed comparability, the new devices with a software package were found to be SE.

Hemodialyzers: This is a class II device that is used as an artificial kidney system. The device allows the removal of water and waste from the patient's blood through a semipermeable membrane. Pre-Amendments devices used cellulose based semipermeable membranes. Manufacturers of post-Amendments devices have used various other types of membrane in the filters and these devices have been found SE. This is because the new membranes raised the same questions of safety and effectiveness as the cellulose membrane, e.g., is the degree of permeability acceptable, is the material toxic, and is the degree of particulate contamination acceptable? Accepted preclinical tests, with clinical confirmation, demonstrated that the new membranes and the cellulose membranes were comparable.

On the other hand, there will be many technological changes that will make a device NSE. For example:

Heart Valves: This pre-Amendment type device is in class III. It is intended to perform the function of any of the heart's natural valves. It is constructed of prosthetic or

biological materials, or both. The Center has found many new valves to be NSE even though the new valves, in some cases, incorporated only very slight design modifications in relation to predicate valves. This is not because the device is a high risk device. Rather, it is because of the nature of the device. A minor change in design can raise questions about safety and effectiveness that are inappropriate for evaluation under 510(k). Specifically, different valve designs can lead to a different balance in the performance factors related to valves. Minor changes in a valve may make it more susceptible to fractures than its predicate, but less susceptible to occlusion. In this case, it is difficult, to compare the performance of one value to another because they present different questions about safety; each valve tends to present different risk/benefit equations. As a result, there are no accepted methods for assessing comparability. Consequently, these devices are typically found NSE.

Electrohydraulic Lithotripter: This pre-Amendments device is in class III. The pre-Amendments device was used to fragment urinary bladder stones. It consists of a high voltage cable connected to a bipolar electrode introduced into the bladder through a cystoscope. The Center found an electrohydraulic lithotripter inserted into the ureter through a cystoscope for use on ureteral stones to be SE. The principle of operation for both devices are identical. The stone is fragmented by the discharge of electricity between the two electrical poles. Another post-Amendments device, known as the Extracorporeal Shock Wave Lithotripter was NSE. This device breaks kidney stones through the use of a succession of externally generated shock waves focused on the stone. The shock waves are transmitted through water, in which the patient is sitting, and then transmitted through body tissue to the stone. The device raised questions about safety and effectiveness not present in the previous devices, e.g., the shock waves, which enter large portions of the body, could affect cardiopulmonary functions or could have had unknown effects on much of the tissue and organs in the

abdomen. An evaluation of these questions was not appropriate for a 510(k) because they presented issues outside the questions of safety and effectiveness raised by the electrohydraulic lithotripter.

Femoral stem: This lower portion of a total artificial hip replacement is a pre-Amendments device proposed for class II. Some of these devices are uncemented and are fixed by impaction of the stem into the top of the femur. The pre-Amendments impact/fit stems had smooth, straight (uncontoured) surfaces on the stem that fit into the femur. The Center found SE some post-Amendments versions of the stem that have surface variations, i.e., grooves, irregular or regular contours, etc., that allow the bone to remodel over time. The Center found to be NSE post-Amendment stems with porous coatings (for uncemented use) that require bone ingrowth into the device fixation. The contoured stem relied on impact placement and bone remodeling to an essentially smooth surface. The health of the bone would still depend upon normal bone vascularization systems even if the bone conformed to some of the slightly wavey contours. The questions of safety and effectiveness were the same as those for the traditional impact fit stem. On the other hand, for bone to grow into, and remain viable in, a porous material, the bone would need to depend upon an intricate vascularization system not normally occurring in bone that may not, in fact, develop or be sustainable. Thus, the porous coated device was found NSE because it presented new scientific questions about long term fixation.

As the examples above illustrate, for a device to be found SE, it is important that a 510(k) for the device either demonstrate that the technology of the device does not differ from the technology of marketed devices within the same type; or, to the extent that the technology does differ: explain why the device does not present new questions about safety or effectiveness, describe what accepted methods exist to test comparability of performance, and present data, generated from such tests, that demonstrate comparability. (See the 510(k) data discussion below. 510(k)s for new devices that are different from

predicate devices, but are not different from a marketed device within the same type, may not need to provide testing information.)

DATA REQUIREMENTS FOR 510(k)s

The requirements of section 510(k) of the act are intended not only to notify FDA that a device is about to be marketed but primarily to enable FDA to determine whether the device is SE to one already in commercial distribution. To fulfill this responsibility, the Center requires that a 510(k) include *descriptive data* needed to understand a new device's intended use, physical composition, method of operation, specifications, performance claims, etc. Similar information about the device to which the new device is being compared may also be required. In addition, under certain circumstances, the Center requires *performance testing information*, i.e., data from bench, animal, or clinical tests, in order to determine that a device performs according to its description.

While the Center has concluded that it should sometimes require performance testing data in order to confirm that a new device is SE, the 510(k) review process is not a substitute for premarket approval, and the Center does not attempt to address all of the issues that would be answered in a PMA in its review of 510(k)s. Data in a 510(k) should show *comparability* of a new device to a predicate device, whereas demonstration, in an absolute sense, of a device's safety and effectiveness, is reserved for PMAs.

Although there are no hard and fast rules governing all the possible data collection issues that can arise in 510(k)s, the following guidance will govern many situations.

The Center will always require descriptive data necessary to understand a new device's intended use, physical composition, method of operation, specifications, performance claims, etc. Also, the Center will always require any descriptive data necessary to understand the same characteristics of the device to which the new device is being compared.

The Center normally will not require performance testing data to substantiate equivalence if a new device does not have an important descriptive difference in comparison to marketed devices within its type i.e., it does not have a new material, method of operation, etc., and it has descriptive characteristics that are precise enough to ensure that comparability will be achieved if the new device is manufactured according to its description. For example, the Center will accept the descriptive statement that a new surgical instrument will be made of surgical grade stainless steel, as are other marketed surgical instruments, as substantiation that the new instrument is equivalent in material/composition to a predicate device. (See below for an explanation of how a comparison to any marketed device can lead to a conclusion about the substantial equivalence of a new device to a predicate device.)

The Center normally will require performance testing data to substantiate equivalence if a new device has an important descriptive difference in comparison to marketed devices within its type, and it is *not* clear from an initial review that the device has an intended use or technological change that makes it NSE; or, the new device has descriptive characteristics that are too imprecise to guarantee that comparability in performance will be achieved even if the new device is produced as described. Following is an example of when descriptive similarities are inadequate to ensure that comparability of performance will be achieved when a new device has the same descriptive characteristics as a marketed device. The fact that a new pacemaker lead and premarketed pacemaker lead are both in the polyurethane "family" does not ensure that both devices have the same chemical formulations, and differences in the chemical formulations of polyurethanes could affect safety or effectiveness. Differences in design, extrusion, and assembly of polyurethanes with the same chemical formulation could also affect safety or effectiveness. Thus, the Center would generally require performance testing information to confirm that the new lead is SE to the predicate lead.

If it is clear from an initial review that a new device has a [*sic*] intended use or technological feature that makes it NSE, the Center will not review or require performance information in the 510(k). Instead the applicant will be notified that the device is NSE, and any performance data will be reviewed in a PMA or reclassification petition.

Typically, 510(k) provides descriptive and testing data that compares the new device to another marketed device within the type, but does not necessarily compare the new device directly to a predicate device. In these cases, the Center can rely, as necessary, on performance data appearing in previously reviewed 510(k) files, in Center classification files, or in the literature, to determine that the device is not only comparable to another marketed device within its type, but is also SE to a predicate device.

Nevertheless, the ultimate burden of demonstrating the substantial equivalence of a new device to a predicate device remains with the 510(k) submitter, and in circumstances when the Center is unfamiliar with certain aspects of the predicate device, the submitter will be required to provide information that substantiates a claim of substantial equivalence.

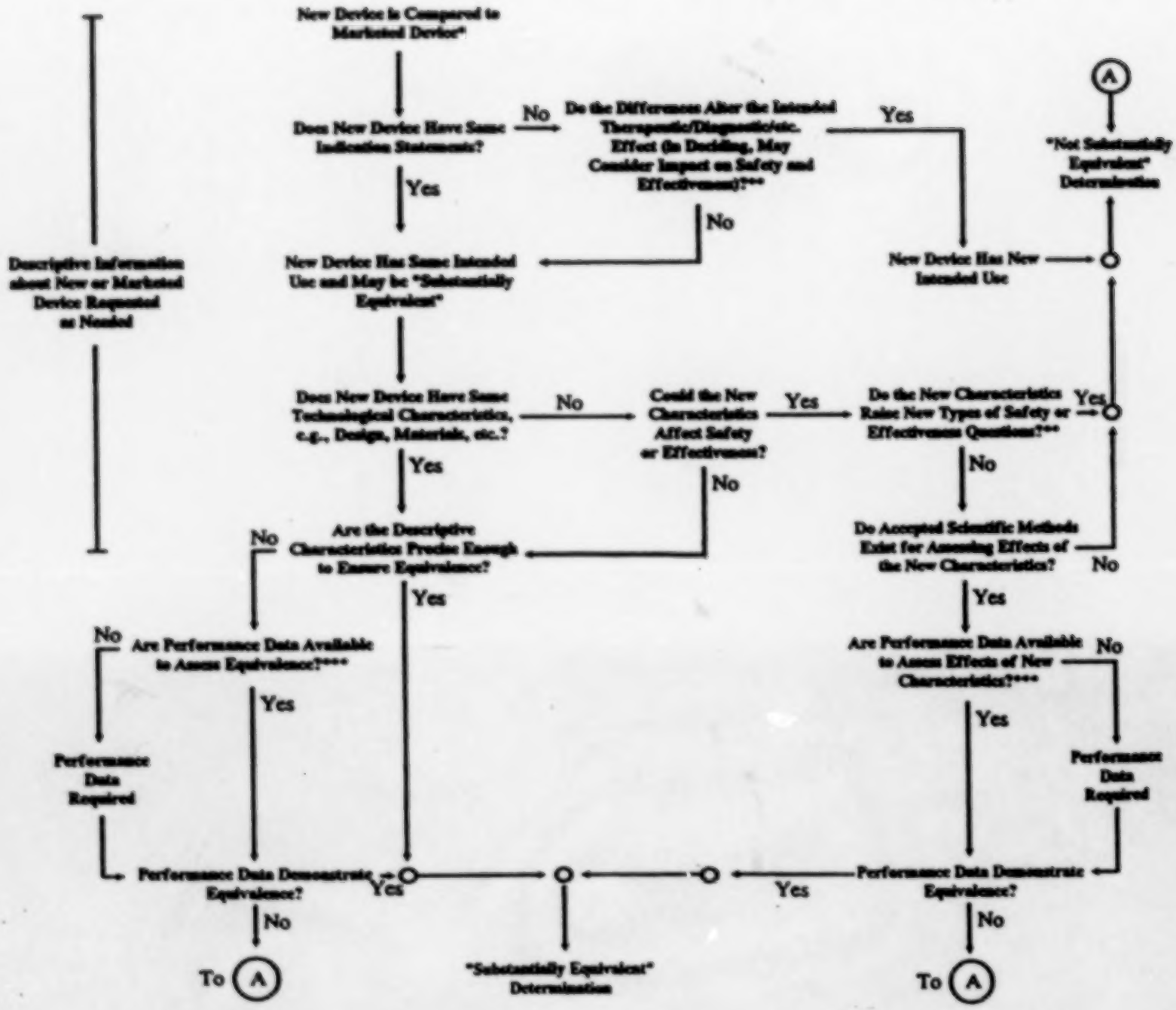
NEW DEVICES THAT ARE COMBINATIONS OF OLD DEVICES

A new device is a so-called "combination" device when it claims to have the same intended uses as two or more different types of predicate devices. Normally, this is achieved by combining two or more predicate devices into a device that is sold as a unit, e.g., a urinary catheter may incorporate a temperature measuring device; or a cardiac monitor, electrocardiograph, and blood pressure computer that were sold separately prior to May 28, 1976, might be combined into one electronic monitoring device.

When a new device combines types of devices from different classes, questions have arisen about what classification the new device will have.

In its review of the 510(k), the Center will subject the combination device to the same sorts of questions and documentation requirements that are applied to a single device. When such a device is found to be SE, it combines devices from different classes and is classified in the highest of the predicate device classifications unless the combined devices are regulatable as separate articles, e.g., they are detachable. In that case, the separately regulatable articles will be regulated in separate classes.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)


New Device is Compared to Marketed Device*
Does New Device Have Same Indications Statements?
No
Do the Differences Alter the Intended Therapeutic/Diagnostic/etc. Effect (In Deciding, May Consider Impact on Safety and Effectiveness)?**
Yes
A
"Not Substantially Equivalent" Determination
Yes
No
Descriptive Information about New or Marketed Device Requested as Needed
New Device Has Same Intended Use and May be "Substantially Equivalent"
New Device Has New Intended Use
Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?
No
Could the New Characteristics Affect Safety or Effectiveness?
Yes
Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?**
Yes
Yes
No
No
Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?
Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?
No
No
Yes
Yes
No
Are Performance Data Available to Assess Equivalence?***
Are Performance Data Available to Assess Effects of New Characteristics?***
No
Yes
Yes
Performance Data Required
Performance Data Required
Performance Data Demonstrate Equivalence?
Yes
Yes
Performance Data Demonstrate Equivalence?
No
No
To A
"Substantially Equivalent" Determination
To A

* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Memorandum

Date: MAR 8 1991 General Program Memorandum #G91-1

From: Director, Office of Device Evaluation (HFZ-400)

Subject: Device Labeling Guidance

To: ODE Review Staff

Purpose

The primary purpose of this memorandum is to formalize guidance to ODE reviewers concerning their review of labeling in device marketing submissions, especially premarket approval applications (PMAs). This guidance is intended to ensure the adequacy of, and consistency in, device labeling information. The guidance is also intended for industry use in preparing device labeling.

Background

General labeling requirements for medical devices have been established in 21 CFR Part 801. Detailed and specific labeling requirements for *in vitro* diagnostic products were promulgated under 21 CFR 809.10. Neither of these, however, provide specific definitions or explanations of some significant terms such as warnings, precautions, contraindications and adverse reactions. The lack of definitions for such terms leads to misunderstandings and disagreements between PHA applicants and the ODE review staff. Because labeling content is a key factor in the CDRH determination of whether there is reasonable assurance that a device is safe and effective for its intended use, such disputes have unnecessarily prolonged PHA review times.

Scope and Application of the Guidance

Portions of the attached "Device Labeling Guidance" that are based upon definitions and requirements in the act and applicable regulations include appropriate references thereto. Guidance on "Indications for Use," "Contraindications," "Warnings," "Precautions" and "Adverse Reactions"

paraphrase applicable provisions in the labeling requirements for prescription drugs (21 CFR Part 201). Consistency between drug and device labeling content and the terminology therein will help minimize misunderstandings by medical practitioners and patients.

While this guidance is primarily intended to ensure the adequacy of, and the consistency in, the labeling information for devices subject to premarket approval, it may also contribute to premarket notification reviews. As indicated in the "Blue Book" 510(k) Memorandum #86-3 dated June 30, 1986, a premarket notification must normally only contain proposed labeling sufficient to describe the device's intended use. Accordingly, the 510(k) decision letter finding a device to be substantially equivalent advises that this finding does not connote approval of the proposed labeling. Nevertheless, in the case of *in vitro* diagnostic devices, devices with special labeling requirements under Subpart H of 21 CFR Part 801, and devices for which the inclusion of specific directions for use, contraindications, warnings, etc. in the labeling may be critical to a finding of equivalence, the ODE premarket notification labeling review includes an evaluation of the compliance of the proposed labeling, or portions thereof, with applicable requirements under 21 CFR Parts 801 and 809, as appropriate.

This guidance was prepared by Charles H. Kyper, Assistant to the Director, Office of Device Evaluation, with input from the CDRH office of Compliance and Surveillance, Office of Health Affairs, and Office of Training and Assistance.

It should be understood that the attached guidance *is not a regulation* and that, as such, variations can occur and should be given appropriate consideration. Based upon the preceding discussion, the need for and usefulness of this guidance should be apparent. ODE reviewers are encouraged to refer to this guidance during labeling reviews and to provide it in correspondence and meetings with representatives of the device industry when appropriate. Reviewers should also keep in mind that this guidance is not intended to limit the consideration of factors that may be specific to the device when reviewing its labeling.

Effective Date: This memorandum is effective immediately.

Robert L. Sheridan

Attachment

DEVICE LABELING GUIDANCE
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- Labeling
- Intended Uses
- Directions for Use

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V. Warnings
VI. Precautions
VII. Special Patient Populations
VIII. Adverse Reactions
IX. Prescription Devices
X. Restricted Devices
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XII. Disclaimer of Liability
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I. Definitions

Label: A "label" is a display of written, printed or graphic matter upon the immediate container of any article. [section 201(k).]

Labeling: "Labeling" includes all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. [section 201(m).]

Intended Uses: The term "intended uses" refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by their expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter,

or oral or written statements by such representatives. It may be shown by the offering or the using of the device, with the knowledge of such persons or their representatives, for a purpose for which it is neither labeled nor advertised. (21 CFR 801.4)

Directions for Use: The term "Directions for use" provides directions under which the practitioner or layman (e.g., patient or unlicensed health care provider), as appropriate, can use the device safely and for the purposes for which it is intended. Directions for use also include indications for use and appropriate contraindications, warnings, precautions and adverse reaction information. Directions for use requirements applicable to prescription and over-the-counter devices appear throughout 21 CFR Part 801 and, in the case of *in vitro* diagnostic products, under 21 CFR 809.10.

II. Safety and Effectiveness Considerations (21 CFR 860.7)

In determining the safety and effectiveness of a device for its intended use, the following factors are to be considered and addressed in the device's labeling by the inclusion of appropriate information:

- The persons for whose use the device is represented or intended;
- The conditions of use for the device, including conditions of use prescribed, recommended or suggested in the labeling or advertising of the device, and other intended conditions of use;
- The probable benefit to health from the use of the device weighed against any probable injury or illness from such use;
- The reliability of the device; and,
- Other relevant factors.

III. Indications for Use

General Statement of Indications for Use

The general statement of the "Indications for Use" identifies the target population in a significant portion of which sufficient valid scientific evidence has demonstrated that the

device as labeled will provide clinically significant results and at the same time does not present an unreasonable risk of illness or injury associated with the use of the device. As appropriate, the labeling should state that the device (trade name) is *"indicated"* or *"intended for use"*

(1) in the treatment, mitigation, prevention or diagnosis of a recognized disease or condition or an important manifestation of a disease or condition; and/or,

(2) in the relief or mitigation of symptoms associated with a disease or condition; and/or,

(3) as an aid or adjunct to a mode of therapy or diagnosis.

Additional information

When indicated or intended for use in selected subgroups of a population with a disease, symptom, or syndrome, the labeling should:

(1) describe the available evidence and state the limitations of usefulness of the device;

(2) identify specific tests needed for the selection or monitoring of the patients;

(3) if available, provide information on the approximate kind, degree and duration of improvement to be anticipated; and

(4) if relevant, include information regarding the recommended intervals between device use, the usual duration of treatment, or any modifications of such.

When safety considerations are such that the device should be reserved or restricted for use in certain situations (e.g., cases not responsive to other devices, surgical procedures or drugs), this information shall be stated.

When there are specific conditions that should be met before the device is used on a long-term basis (e.g., demonstration of responsiveness to the device in a short term trial), the labeling should identify the conditions or, if the indications for long-term use are different from those for short-term use, the labeling shall identify the specific indications for each use.

When there is a common belief that the device may be effective for a certain use or there is a common use of the

device for a condition but the preponderance of evidence related to the use or condition demonstrates that the device is ineffective, FDA may require that the labeling state that there is a lack of evidence that the device is effective for that use or condition.

IV. Contraindications

This section describes situations in which the device should not be used because *the risk of use clearly outweights* [*sic*] *any possible benefit.* Examples that may, but not always, contraindicate the use of a device include:

— Hypersensitivity to an ingredient of a permanently implanted device;

— Substantial risk of being harmed because of age, sex, concomitant therapy, disease state or other condition; or,

— Continued use in the face of an unacceptably hazardous adverse reaction.

Known hazards and not theoretical possibilities are to be listed, e.g., if hypersensitivity to an ingredient in the device has not been demonstrated, it should not be listed as a contraindication. The "Contraindications" section shall immediately follow the "Indications for Use" section of the labeling. If no contraindications are known, this section of the labeling should state "None known."

V. Warnings

Describe *serious adverse reactions* and *potential safety hazards, limitations in use* imposed by them, and *steps that should be taken* if they occur.

Include an appropriate warning if there is *reasonable evidence of an association* of a serious hazard with the use of the device. *A causal relationship need not have been proved.*

A warning is appropriate when the device is commonly used for a disease or condition for which there is a lack of valid scientific evidence of effectiveness for that disease or condition and such usage is associated with a serious risk or hazard.

VI. Precautions

Include information regarding *any special care to be exercised* by the practitioner and/or patient for the safe and effective use of the device, for example:

— Indicate or emphasize any need for proetective wear during use.

— Identify any laboratory tests or other evaluations that may be helpful in following the patient's response or in identifying adverse reactions and, if appropriate, specify the frequency of such tests or evaluations before, during and after use of the device.

The "Precautions" section of the labeling includes precautionary statements not appropriate for inclusion under other sections of the labeling. Additional guidance regarding precautions will be found in the "Special Patient Populations" section below.

VII. Special Patient Populations

Limitations on the usage of a device may be necessary for various reasons including lack of long-term safety and effectiveness data, lack of safety and effectiveness data for specific patient populations (e.g., pregnant women), growth processes still occurring in the body, and anatomical or physiological limitations on the effectiveness of the device. If the safety and effectiveness of the device for use in specific patient populations have not been established on the basis of valid scientific evidence, the "Indications for Use" section shall specifically identify the persons for whose use the device is indicated and the "Precautions" section shall include the following statement:

> "Safety and effectiveness in (e.g., pregnant women, children under the age of . . . , etc.) have not been established."

If use of the device in a certain patient population is associated with a specific hazard, the hazard shall be described in the "Precautions" section or, if appropriate, the hazard shall be stated in the "Warnings" or "Contraindications" section

and the "Precautions" section of the labeling shall refer to it, e.g., "See 'Warnings' section for information on . . . . ."

VIII. Adverse Reactions

An adverse reaction is *an undesirable effect, reasonably associated with the use of the device,* that may occur as part of the effect of the device or may be unpredictable in its occurrence.

This section includes *all* adverse reactions reasonably associated with the use of the device, including those mentioned in the "Contraindications", "Warnings" and "Precautions" sections of the labeling. The listing of the adverse reactions should be followed, if appropriate, by statements directing the reader to other sections of the labeling for additional information regarding these adverse reactions and any steps that should be taken.

Adverse reactions should be listed in descending order according to their clinical significance as determined by their severity and frequency. Provide frequency data from adequately reported clinical studies when the data is not well known to the device user (practitioner and/or patient) and/or when needed in deciding between the use of the device and an alternative procedure or approach.

IX. Prescription Devices

A prescription device is, by definition under 21 CFR 801.109, a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of the device, and hence for which "adequate directions for use" (21 CFR 801.5) cannot be prepared.

A prescription device, other than surgical instruments, is misbranded if its label does not bear:

(1) the statement, "Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to be filled with the word "physician", "dentist", or with the descriptive designation of any

other practitioners licensed by the law of the State in which that person practices to use or order the use of the device; and

(2) the method of application or use of the device.

A prescription device is misbranded if its labeling does not bear:

(1) information for use including indications, effects, routes, methods, frequency and duration of administrations, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented, with the exceptions that

(a) such information may be omitted from the dispensing package if, but only if, the directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device and the FDA Commissioner is requested to offer an opinion on a written proposal stating reasonable grounds to omit such information from the dispensing package;

(b) such information will not be required on so called reminder-piece labeling which calls attention to the name of the device but does not include indications or other use information: and

(2) the date of the issuance or the latest revision of the labeling, except for labels and cartons, that bears directions for the use of the device.

X. Restricted Device

Under the authority of section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act), the approval order for a premarket approval application (PMA) may require, as a condition of approval, that the sale, distribution and use of the device be restricted but only to the extent permitted under section 520(e) of the act. Under section 520(e) of the act, FDA may require that a device be restricted to sale, distribution and use only upon the written or oral authorization of a practitioner licensed by law to administer or use such devices (i.e., prescription device) or upon such other conditions that FDA may prescribe. Such a requirement must be based upon a determination by FDA that, because of the device's potentiality for harmful effect or the collateral measures necessary to its use, there cannot otherwise be reasonable assurance of its safety and effectiveness. If the device is restricted to use by persons with specific training or experience in its use or by persons for use in certain facilities, FDA must determine that such a restriction is required for the safe and effective use of the device. A person cannot be excluded from using a device, however, solely because that person does not have the training and experience to make him/her eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board.

When the sale, distribution and use of a device are restricted in a PMA approval order or by regulation under section 520(e) of the act, the label must include appropriate statements of the restrictions imposed by FDA (e.g., restrictions on the sale, distribution and use of the device or restrictions on the use of the device to persons with specific training or experience in its use or to persons for use in certain facilities). The label shall bear the statement, "Caution: Federal law restricts this device to sale, distribution and use by or on the order of a _____", the blank to be filled with the word "physician", "dentist", or with the descriptive designation of any other practitioners licensed by the law of the State in which that person practices to use or order the use of the device and, if applicable, followed by a descriptive phrase of the training or experience required (e.g., "trained and/or experienced in _____", the blank to be filled with, as appropriate, "the use of this device" or specified therapeutic or diagnostic procedures) and/or the facilities to which use is restricted.

In accordance with the provisions of section 502(r) of the act, advertisements and other descriptive printed material

issued by the manufacturer, packer or distributor with respect to a restricted device must include the following among other things:

(1) a true statement of the device's established name (common or usual name unless there is an official name designated by FDA or recognized in an official compendium), printed prominently and in type at least half as large as that for any trade or brand name for the device; and

(2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.

Except in extraordinary circumstances, FDA cannot require prior approval of the content of any advertisement except in the case of any printed matter which FDA determines to be labeling as defined in section 201(m) of the act.

XI. Patient Information Labeling

Patient information labeling includes labeling directed to the patient as well as family members and others who administer home use devices to patients, e.g., care providers who oversee the use of infant apnea monitors and nebulizers. In determining whether patient information labeling is appropriate for a prescription device, the folloving factors, among others, should be considered:

— Should the patient be aware of alternative(s) to the use of the device if a choice is available?

— Are substantial risks or discomforts associated with the use of the device?

— Is the need for strict patient adherence to a specific treatment regimen required?

— Does substantial public or professional controversy exist about the device and its related procedures?

Patient information labeling shall include the indications for use and relevant contraindications, warnings, precautions and adverse reactions using terminology well known and understood by the average layman. Technical terms should be kept to a minimum and should be defined when necessary. If applicable, directions to ensure safe and effective use of the

device by the patient shall be included. Patient information labeling, if possible, should not exceed the seventh grade reading comprehension level.

The following sources may provide useful information regarding the information to be included as well as the terminology to be used in patient information labeling:

1. U.S.P. Dispensing Information, Volume II, Advice for the Patient®, Drug information in Lay Language
2. American Medical Association Drug Evaluations

XII. Disclaimer of Liability

Inclusion in the labeling of a disclaimer regarding the safety and effectiveness of the device for its indicated or intended use is to be avoided. Instead, labeling and promotional material may include an objective and accurate representation of the clinical experience with the device whereby the practitioner and patient are made aware not to expect a completely safe and effective outcome with the use of the device in all cases.

Inclusion of disclaimers of liability for any medical expenses or any direct or consequential damages resulting from or caused by any defect, failure or malfunction of the device will not inhibit FDA in imposing the notification and other remedies (repair, replacement or refund) provisions of section 518 of the act. The provisions of section 518 may be imposed whenever FDA determines that:

(1) The device presents an unreasonable risk of substantial harm to the public health;

(2) There are reasonable grounds to believe that the device was not properly designed and manufactured within the state of the art; or

(3) There are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than the manufacturer, importer, distributor or retailer of the device to exercise due care in the . . . use of the device.

XIII. Misbranding

Pertinent provisions in the law and implementing regulations related to medical device labeling and enforced by FDA appear below. It is important that these provisions be kept in mind both in the development of labeling by the device industry and in the labeling review by CDRH.

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) provides that a device shall be deemed misbranded if:

(1) Its labeling is false or misleading in any particular.

(2) The label does not bear the name and place of business of the manufacturer, packer or distributor and an accurate statement of the quantity of contents in terms of weight, measure or numerical count.

(3) Any required word, statement or other information to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(4) Labeling does not bear adequate directions for use and such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users.

(5) In the case of a restricted device, its advertising is false or misleading in any particular.

(6) In the case of a restricted device, advertisements and other descriptive printed matter (other than labeling) issued by the manufacturer, packer or distributor do not include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

In determining whether a device is misbranded because the labeling or advertising is misleading, section 201(n) of the act permits the following to be taken into account among other things:

(1) representations made or suggested by statement, word, design, device, or any conbination thereof; or

(2) the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to the consequences which may result from the use of the device to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising or under such conditions of use as are customary or usual.

Regulations applicable to medical devices provide that the inclusion of any of the following representations in device labeling constitutes misbranding of the device:

21 CFR 801.6 — False or misleading representation with respect to another device or a drug

21 CFR 807.39 — Any representation that creates an impression of official approval because of registration or possession of a registration number (e.g., inclusion of FDA establishment registration number)

21 CFR 807.97 — Any representation that creates an impression of official approval because of complying with the premarket notification regulations (e.g., inclusion of premarket notification reference number)

XIV. Prohibited Acts

Section 301(1) of the act prohibits the use in any labeling or advertising for the device of any representation or suggestion that approval of an application with respect to the device is in effect under section 515 of the act (premarket approval) or that the device complies with the provisions of section 515.

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DHHS/PHS/FDA/CDRH
DIVISION OF GENERAL AND RESTORATIVE DEVICES
9200 CORPORATE BOULEVARD, HFZ-410
ROCKVILLE, MARYLAND 20850

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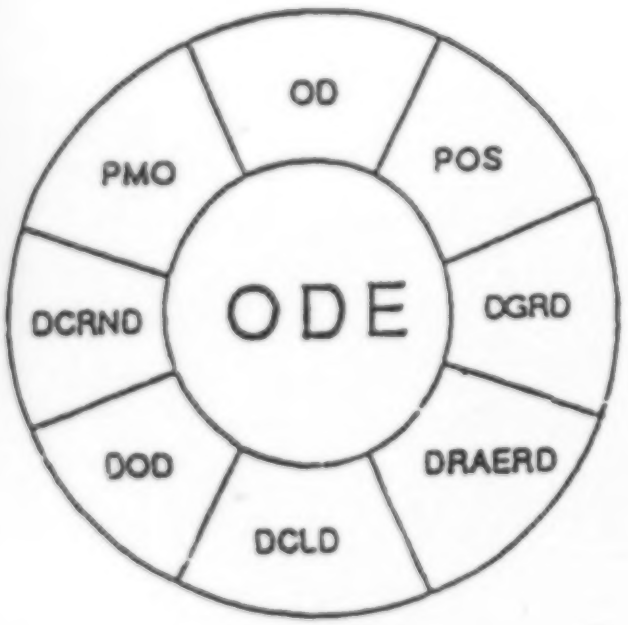
JAN 10 [illegible]



FROM: Mark N. Melkerson

DATE: 1/10/95

NO. OF PAGES:

PHONE NO: 301-594-

FAX NO: 301-594-2358

TO: Richard Trehearne, Ph.D. / Reg Affairs

FAX NO: 901-346-9738

SUBJECT: K932029

ADDITIONAL COMMENTS: Suggested Labeling Changes To Address Adequate Directions For Use, Limitations of Documented Pre Amendents Device Indications, and Potentially Misleading Claims or Statements. I Will Call You Regarding This F.
Mark

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

treatment of severe spondylolisthesis (Grade 3 and Grade 4), the specific indications ~~are as follows:~~ FOR SACRAL/ILIAC SCREW ATTACHMENT AND/OR ANTERO LATERAL SCREW ATTACHMENT ARE THE FOLLOWING:

1. Degenerative disc disease. [DEFINE CHARACTERISTICS]
2. Idiopathic scoliosis.
3. Neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity.
4. Spinal fractures (acute reduction or late deformity).
5. Tumors.
6. Spondylolisthesis.
7. Stenosis.
8. Pseudoarthrosis.
9. Unsuccessful previous attempts at spinal fusion.

INSERT #1 -VE UP TO FIRST PAGE

The TSRH Spinal System, with the Variable Angle and Central Post Screws, is ~~also~~ indicated for ~~anterior~~ fixation in patients with severe spondylolisthesis (Grade 3 and Grade 4) receiving ~~fusion with~~ autogenous bone graft, ~~to be fixed or attached to the lumbar and sacral spine,~~ and to be removed after the development of a solid fusion mass.

INTO THE PEDICLES OF THE L5 VERTEBRAE AND/OR SACRAL/ILIAC ATTP
IS

NOTA BENE: The TSRH Spinal System is limited to non-cervical use. ~~Except for~~ The TSRH Staples, ~~all of the components of the TSRH Spinal System are intended for posterior spinal fixation.~~ The TSRH Variable Angle Screws and TSRH Central Post Screws, when used with the TSRH Spinal System, may also be inserted into the pedicles of the lumbar ~~spine~~ from a posterior surgical approach for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) in association with the use of autogenous bone graft, ~~otherwise their use is~~ for sacral/iliac attachment only. All of the TSRH hooks are intended for posterior thoracic and/or lumbar use only. All the CROSSLINK Plates are intended for posterior thoracic and/or lumbar use only.

ARE INTENDED FOR ANTERO LATERAL USE ONLY.
FIFTH (L5) VERTEBRAE
THE TSRH VARIABLE ANGLE AND CENTRAL POST SCREWS, WHEN USED IN POSTERIOR FIXATION ARE

ATT. IS INTE TO R REM AFTE DEVELOPI OF A SOLI FUSION

Appendix E — Preemption Provisions Contained in Precursor Legislation to the MDA

H.R. 9984 (as introduced in House of Representatives, August 3, 1973):

EFFECT ON STATE REQUIREMENTS

Sec. 903. (a) Whenever a standard pursuant to section 513 or scientific review pursuant to section 514 under this Act is in effect no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the requirements of the Federal requirements.

93d Cong., 1st Sess. at 63 (1973) (never brought to vote)

S. 2368 (as passed Senate, February 1, 1974):

EFFECT ON STATE REQUIREMENTS

Sec. 903. (a) Whenever a performance standard pursuant to section 513 or scientific review pursuant to section 514 under this Act is in effect, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the Federal requirements.

93d Cong., 2d Sess. at 73-74 (1974) (introduced Aug. 3, 1973; passed Senate Feb. 1, 1974, 120 Cong. Rec. 1783; never brought to vote in House of Representatives)

S. 510 (as passed Senate, April 17, 1975):

EFFECT ON STATE REQUIREMENTS

Sec. 903. (a) Whenever a performance standard pursuant to section 513 or scientific review pursuant to section 514 under this Act is in effect, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the Federal requirements.

94th Cong., 1st Sess. at 73-74 (1975) (introduced Jan. 30, 1975; passed Senate Apr. 17, 1975, 121 Cong. Rec. 10688; entire text deleted by House and text of H.R. 11124 substituted; passed by House of Representatives as amended Mar. 9, 1976, 122 Cong. Rec. 5848; House-Senate Conference agreed to pertinent House amendments May 6, 1976, H.R. Rep. No. 1090, 94th Cong., 2d Sess. at 51 (reprinted at 1976 U.S.C.A.A.N. 1070, 1103); conference bill passes both House of Representatives and Senate May 13, 1976, 122 Cong. Rec. 13777 and 14005; signed into law May 28, 1976, 90 Stat. 539)

H.R. 5545 (as introduced in House of Representatives, March 26, 1975):

STATE AND LOCAL REQUIREMENTS
RESPECTING DEVICES

General Rule

Sec. 521. (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

94th Cong., 1st Sess. at 74-75 (1975) (never brought to vote)

S. 2697 (as introduced in Senate, November 20, 1975):

EFFECT ON STATE REQUIREMENTS

Sec. 608. (a) Whenever a performance standard pursuant to section 602 or scientific review pursuant to section 603 under this Act is in effect, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the Federal requirements.

94th Cong., 1st Sess. at 170-71 (1975) (never brought to vote)

H.R. 11124 (as reported by the House of Representatives, February 29, 1976):

STATE AND LOCAL REQUIREMENTS
RESPECTING DEVICES

General Rule

Sec. 521. (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

94th Cong., 2d Sess. at 87 (1976) (introduced Dec. 11, 1975; entire text substituted for S. 510 and passed by House Mar. 9, 1976, 122 Cong. Rec. 5848; signed into law (as S. 510) May 28, 1976, Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539)

S. 510 (as enacted into law, May 28, 1976):

STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES

General Rule

Sec. 521. (a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Pub. L. No. 94-295, 90 Stat. 539